EXHIBIT 5

In The Matter Of:

In Re: CR Bard 200

Daniel Elliott, M.D.

November 15, 2014

Tiffany Alley Global Reporting & Video

730 Peachtree Street NE

Suite 470

Atlanta, GA 30308

770.343.9696

www.tiffanyalley.com

IN THE UNITED STATES DISTRICT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C.R. BARD, INC.,
PELVIC REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL
CASES IN MDL NO. 2187 AND
SPECIFICALLY TO:

_____

ROSAIDA ALONSO,
Plaintiff, Civil Action File
No. 2:14-cv-07112
vs.

C.R. BARD, INC.,
Defendant.

_____

PATRICIA BOLYARD, et al.,
Plaintiffs, Civil Action File
No. 2:12-cv-00126
vs.

C.R. BARD, INC.,
Defendant,

_____

MARTINA WHEELER,
Plaintiff, Civil Action File
No. 2:12-cv-04580
vs.

C.R. BARD, INC.,
Defendant.

The videotaped deposition of DANIEL S. ELLIOTT, M.D.,

November 15, 2014

Wexler Wallace, 55 West Monroe Street, Suite

3300, Chicago, Illinois, commencing at 9:23 a.m.

Reporter: Jennifer L. Bernier

.

APPEARANCES:

WAGSTAFF & CARTMELL
MR. THOMAS CARTMELL
MR. JEFFREY M. KUNTZ
4740 Grand Avenue
Suite 300
Kansas City, Missouri 64112
Phone: (816) 701-1100
E-Mail: tcartmell@wcllp.com
jkuntz@wcllp.com
-AND-
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
MS. P. ANN GAYLE
MR. BRANDON S. MORRIS
17 East Main Street
Suite 200
Pensacola, Florida 32502
Phone: (850) 202-1010
E-mail: agayle@awkolaw.com
bmorris@awkolaw.com
On behalf of the Plaintiffs;
REED SMITH
MS. MELISSA GEIST
136 Main Street
Suite 250
Princeton Forrestal Village
Princeton, New Jersey 08540
Phone: (609) 514-5978
E-mail: Mgeist@reedsmith.com

On behalf of the Defendant.

ALSO PRESENT:

John Doody, Videographer

I N D E X

E X H I B I T S

VIDEO TECHNICIAN: We're now on the record. The time is approximately 9:23 a.m. This is the beginning of Disc 1 for the video deposition of Dr. Daniel S. Elliot.

Will counsel please identify yourselves for the record and state who you represent.

MR. CARTMELL: Tom Cartmell for the plaintiffs.

MR. KUNTZ: Jeff Kuntz for the plaintiffs.

MS. GEIST: Melissa Geist for the defendant, C.R. Bard.

VIDEO TECHNICIAN: Would the court reporter please swear in the witness.

(Witness sworn.)

WHEREUPON:

DANIEL S. ELLIOT, M.D.,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. GEIST:

Q. Good morning, Dr. Elliott.

A. Good morning.

Q. We met just before the deposition, correct?

A. Correct.

Q. As I told you then, my name is Melissa Geist. I'm with the law firm of Reed Smith and we represent

C.R. Bard in the MDL proceeding in West Virginia entitled C.R. Bard Repair System Products Liability Litigation. And you've been designated by the plaintiffs in that litigation as an expert witness with respect to certain general liability opinions, correct?

A. Correct.

Q. And you understand we're here today to take your deposition in that litigation?

A. Correct.

Q. And it's my understanding that today, Doctor, we'll focus on your general liability report, and then tomorrow we'll focus on your case-specific opinions that you've rendered in three cases. Is that your understanding as well?

A. Yes.

(Elliott Exhibit Nos. 1 & 2 were marked for identification.)

BY MS. GEIST:

Q. I've marked, as Exhibit 1 to your deposition, Doctor, the notice for today's deposition. Do you see that?

A. Yes, I do.

Q. And I've also marked, as Exhibit 2, a copy of your general liability expert report in this litigation. And do you see that as well?

Page 6

A. Yes, I do.
Q. That -- that expert report you have in front of you, Doctor, that's the only expert report you've provided in this litigation other than the three case-specific reports, correct?
A. Correct.
Q. Does it contain a complete statement of all of the opinions you hold in the litigation?
A. As of this point right now.
Q. Do you intend to offer any opinions that are not set forth in your expert report that's been marked as Exhibit 2?
A. Only if new information were to become available to me.
Q. But at least as of this point, as we're sitting here today, all of the opinions that you intend to give, if you were called as a witness in this trial, for example, are contained in that report; is that fair to say?
A. Correct. And, again, unless you ask another question that has not been addressed in this, yes.
Q. Are all of the facts and the data that you considered in reaching your opinions in this litigation also contained in that report or in the Materials Relied section of that report?

Page 7

A. As far as the internal documentation, yes. That's all. I've read all of those documents. However, as far as experience, personal conversations, surgical experience, you know, that's not going to necessarily be accurately reflected in the -- in my CV or in these reliance issues.
Q. Yep, and that's fair, Doctor. But my question really is, all of the documents, the literature and other documents that you considered in reaching your opinions, are all of those set forth in the reliance list that's attached to your report?
A. I'd say that's a fairly accurate issue. I can't attest that there hasn't been some other document, medical research literature, that I've read at some point in time that's not included in here. But as far as to answer your question, this is a very complete list of medical literature.
Q. Yesterday or the day before yesterday -- well, certainly in the last couple of days -- we received an updated reliance list containing another 120-or-so medical articles that counsel stated also formed -- helped you form the opinions you reached in this litigation. Are you aware of that?
A. Yes, I am.
Q. And do you have that updated list with you?

Page 8

A. Yes, I do.
Q. Is that there on your laptop?
A. No. The laptop has the Dropbox accounts of all of the internal documents. The document I brought here, which is the updated bibliography, is exactly what you have.
Q. Okay. So you have it there in front of you in paper copy?
A. Correct.
Q. So why was there an update in the last couple of days?
A. Because I'm constantly doing research. I'm constantly going to meetings. I'm constantly in conversations with colleagues. So there's constant progression of knowledge.
Q. So when did you read all of the new materials that are set forth in your updated reliance list?
A. At some point in time between when this was turned in until now. So that was October 8th, when this was turned in originally, until -- well, I'm constantly doing research just as part of my normal workday.
Q. So between October 8th and now, which is November 15th, right?
A. Yes.
Q. So in the last four or five weeks or so, you

Page 9

reviewed an additional, by my count, at least 120 new articles?
A. Sounds about right. But I'm a reviewer for 15 different journals, national/international journals, and I attended a meeting between that time. So that's about average.
Q. So I just want to make sure you answered my question. All of the articles that were included in your updated reliance list, and, by my count -- and this is an estimate. I'll let you know that, Doctor -- there's about, at least, 120 new articles?
A. Again, that sounds about right, but the total is 509 articles.
Q. So for the 120-or-so new articles, you read those in the last four weeks or so?
A. Yes.
Q. How did you come across the new articles?
A. PubMed searches or as journals come out, the International Urogyn Journal comes out, the Journal of Urology comes out. I looked an article and that has references. A good example of that would have been the Zimmerman article, because then that spurs more ideas in looking at what their references are.
Q. So you'll agree with me, I'm sure, Doctor, that some of the 120 or so new articles are not new

Page 10

publications, right?
A. Correct.
Q. They go back to 2006, 2008, and earlier for some of them?
A. Correct.
Q. Did -- and you said you did this during your own PubMed search?
A. Correct.
Q. And did you do a PubMed search prior to the time you rendered your expert opinions in this report?
A. Oh, absolutely. I've used PubMed. There's 24 million articles in it, so we're using it. That's my main search engine.
Q. So I'm trying to understand why all of the new articles weren't included on your original reliance list.
A. Because I'm constantly working on this. This is what I do day in and day out as far as taking care of patients. Patients come in with new problems. I attend meetings. I just got back from a meeting, the South Central Section of Urology. There's presentations. So it's not a stagnant. We are constantly trying to learn to better handle this problem.
Q. So let me make sure I understand that. Like we just agreed, some of the articles date back a long

Page 11

time ago, right?
A. Correct.
Q. Did you miss them during your original PubMed review?
A. No. That's a very unfair statement to say, I've missed something. These are new articles that have come out. Like Dr. Zimmerman's article, Mickey Karram's article. And they make references to other articles, and so we go back and look at that literature.
Q. So all of the new articles that were added to your updated list are here because they were all referenced in brand-new publications that you hadn't found during your first search.
A. That's not what I'm saying. As far as this is a vast topic, a lot of people are writing on it, national and international. And so we can't, on the first search through, get every single article. Also, as we go along, we start learning about pain. I start going into -- I'm a member of the International Pelvic Pain Society, okay. So that gets more articles and more reading.
Q. Did you focus on any particular topic or subject area when you did your updated PubMed search?
A. Pelvis, pelvic pain, pelvic pain management, pelvic mesh management, pelvic complications. So each

Page 12

time you do one of those searches -- remember, search 24 million articles, okay. So each time I do a variant of that search, just like you do a Google search with different changing words, different articles will pop up.
Q. Well, did the search terms you used during this recent PubMed search differ from the original search terms you used?
A. There may be different ones there. But if PubMed is screening all journals from around the world, journal articles will be popping up differently. So it's not a stagnant. Knowledge is not stagnant. It's constantly progressing forward.
Q. Well, you would agree with me, Doctor, that the knowledge, as you say, included in some of these articles date back more than ten years ago, right?
A. Some date back to the '70s. Some date back probably even earlier than that.
Q. Did your review of the additional publications change or amend or revise your opinions in this litigation in any way?
A. They probably will reinforce or further -- further deepen the knowledge of the subject. But the human pelvis is incredibly complicated. The neurologic aspects are incredibly complicated. So, again, it's a

Page 13

deepening of the knowledge.
Q. Did -- did you feel that you had missed anything the first time around?
A. No. I wouldn't say I missed anything; but, again, it's adding to that, the body of knowledge.
Q. Do you feel that you needed to go back and do additional research or reading on any particular topic or subject area?
A. I wouldn't say that, but I'm always open. If there's new data that comes out, I'm always open. I'm not going to keep a closed mind about anything.
Q. Did you review all of the articles and literature that are contained on your original and updated reliance list?
A. Yes.
Q. And there is also some depositions listed on your reliance list, correct, Doctor?
A. Yes.
Q. Did you review the entirety of those depositions or did you review excerpts?
A. I would scan over the entire documents. Certain aspects of them are applicable to me, and then also these documents are, some of them, 500-or-more pages long. So I can't say I read every single word, but I would scan through them or find keywords that I

Page 14

was searching for.
Q. So you didn't read the entirety of the deposition transcripts that are listed on your reliance list?
A. I can say I scanned over every single page of those documents. Did I read every single word? The answer to that is, no.
Q. But when you say scan, what are we talking about? You flipped through and you looked for certain keywords?
A. I'm saying I have it on the desktop and I go through the keywords. I search for keywords. I search for various different phrases. As you know, certain of these depositions, they will go on for 20 or 30 pages talking about this type of stuff, which I don't -- I don't read every word of.
Q. So you didn't actually sit down and review or read the transcripts. You used your computer and you picked out certain search terms. And then when those search terms hit in the transcript, those are the pages you looked at?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Yeah. That's not what I said. I said I sat down. Whether I do it with a paper copy or on a

Page 15

computer -- I suspect you don't print out every single deposition and neither do I. So I go through every single page.
Q. And were you given the entirety of the transcripts?
A. As far as I know. I see a beginning and an end and where they sign off.
Q. How about the exhibits to the depositions? Did you review all of the exhibits to the depositions?
A. Yeah. Either I have reviewed the exact document or where it's referenced in the deposition where they discuss it.
Q. So are you telling me you didn't necessarily review the exhibit, itself, if it was referenced in the deposition testimony?
A. If all there is is a quick reference to something, a manuscript, well, then I'll review that one in detail. If it's an e-mail where they're using a specific quote, I'll review that, the e-mail before and the e-mail afterwards, so I can't pick. You know, as you know, there's thousands of pages of depositions there. Okay. I have looked at them all. I can't remember them all by any means.
Q. So my question actually referred to the exhibits.

Page 16

A. Correct.
Q. So did you read every single exhibit for all of the depositions listed on your reliance list, or no?
A. I can't recall. There's too many there.
Q. You don't remember if you read every single one or not?
A. No, I can't recall that.
Q. That was something that was added to your updated reliance list, correct, the list of exhibits?
A. Correct. Yes. And the added ones I know because they came in relatively recently. I've gone through every single one. I can't speak to all of them in the entirety of this whole project, though.
Q. Well, before you originally provided your expert report with your reliance list, you didn't include, as part of the documents you relied on, the exhibits to the depositions, right?
A. Again, I have not gone back and compared the one prior to October 8th and then the present. So I don't know which ones were there. So I can't answer your question accurately.
MR. CARTMELL: And just so you know, Melissa, that, I believe, was because obviously we, as lawyers, helped put that together, and that was, I think, an omission by us.

Page 17

MS. GEIST: So -- thank you, Counsel.
BY MS. GEIST:
Q. So let me ask you that, Doctor. How did your reliance list come to be prepared? Did you prepare it yourself?
A. The bibliography, the manuscripts reviewed, I completed that one completely myself. The documents, the internal documents with the Bates numbers, those were provided to me. And then how they organized them, I did not do that.
Q. Okay. Well, you have it in front of you, don't you, Doctor?
A. Yes.
Q. Let's -- and you can look at your updated one. It doesn't matter to me which one you look at.
A. The reliance list I don't have with me. I'll go off of this copy here.
Q. Okay. Let's just go through it sort of methodically, shall we? Do you have it there in front of you, Doctor?
A. Yes, I do. Yeah. I have the reliance list starting with the Bard documents.
Q. Great. Okay. So the reliance list starts with a list of Bard documents, as you've just indicated, and most of them are preceded with what we call a Bates

stamp, right, an AVA number?
A. Correct.
Q. Do you see that? And the list goes on for a few pages, right?
A. Correct.
Q. So all of the -- all of the documents that are reflected here, on this part of your reliance list, were provided to you by counsel, correct?
A. Well, yes. It has a Bates number on it. I would have no access to that otherwise.
Q. Okay.
A. So, yeah, that was provided by the lawyers.
Q. Okay. So fair to say that the lawyers selected which of the Bard documents that you were reviewing in order to inform your opinions?
A. No. That would be incorrect. I asked -- I was very clear with the lawyers. I wanted provided all information, pro and con, concerning the situation at hand with the mesh product, the Avaulta mesh. These were provided to me by the lawyers. So I can't say. Again, that's what I asked. This is what was provided.
Q. After you reviewed the documents that were selected for your review by counsel, did you ask for any additional Bard documents?
A. Absolutely.

Q. And do you know, from looking at this list, which of the documents you asked for?
A. Well, no. Not -- based upon these numbers, no, I would not be able to tell that.
Q. Okay. How about generally speaking? Do you remember sitting here today, after you reviewed the initial set of Bard documents that were provided to you by the plaintiffs' lawyers, what else did you ask to look at?
A. Again, this has been going on for, what, four or five months now, so I can't speak specifically to all that I asked for. Most specifically, from my expert report concerning the MSDS, I wanted to review in detail all of the internal documents pertaining to the e-mails exchanged concerning the resin toxin, et cetera. So that's the one I can think of off the top of my head. I can't think of all of the others. This has been going on too long to know all of the specifics, but that one I know I did ask for.
Q. All right. So you asked for additional information, internal e-mails, on the MSDS issue?
A. I asked for all of the available information on this situation. So let's put it that way. And that was what was provided to me.
Q. Okay. So just so I understand, you saw the

MSDS issues, so to speak, in some of the documents you were provided initially, correct?
A. Correct.
Q. And then, in response to that, you said, Hey, Counsel, give me everything on this issue. I want to review the whole topic. Is that fair to say?
A. Partially. I reviewed the issue. I wanted to make sure I had all of the documents, whether or not more were there and not provided yet or if I did have all of the documents, because I never know if I'm getting all of the documents. I don't know what else is out there. That's why I always ask for all.
Q. Right. So that was my question. You don't know if you have all of the documents on the issue, correct?
A. Well, of course not. I don't know if I have all, but I have asked for all.
Q. You've asked for all?
A. Correct.
Q. Okay. Any other topics, like the MSDS topic, that you can think of that you asked for additional information about?
A. Actually, yes. I can think of another one pertaining to pore size. Again, it was the same as the other issue. I asked for all documents, what they had,

based upon the internal documentation of the pore size of the mesh of the Avaulta Plus, the Avaulta Solo. Also, on the -- what was known. I wanted to know all of the issues. There's biocompatibility studies pertaining to the products, all of the Bard products.
And as I go down my list -- oh, and, also, the last one, as far as the IFUs, I wanted to be provided all of the IFUs, not just a specific year. Because, again, I don't know what versions of IFUs are out there, so I asked for all of the IFUs regardless of date.
Q. So just to recap, in addition to the MSDS issue, you wanted to make sure, before you informed your opinions, that you had all of the documents on the pore size issue, correct?
A. Well, on that one specific issue, yes. I just wanted to be provided with everything.
Q. And the same with biocompatibility? You wanted to look at all of the studies relating to biocompatibility for the Bard products?
A. Correct, related to its 510(k) submission.
Q. And the same thing with the IFUs, Doctor? You wanted to see all versions of the IFUs for both the Avaulta anterior and posterior products?
A. Yeah, all of the Avaulta products, yes. And the ones that I listed there are the ones I can think of

Page 22

off the top of my head. If I were to go through the entire expert report, we'd probably come up with more.

Q. And were you provided additional information as you asked for it?

A. If it had been available. Sometimes I already had all of the information.

Q. Now, flipping with me, Doctor, to the section of your reliance list entitled Depositions-Testimony.

A. I have the section. It doesn't have a page number, but it just says, Depositions.

Q. Okay. And, Doctor, you're looking at what we've marked as Exhibit 2, which is your generic expert report, correct?

A. Correct.

Q. And with that report came the original reliance list, right?

A. Correct.

Q. And you have in front of you there a paper version of the updated reliance list, correct?

A. What you've provided me today, yeah. I don't have a personal copy of the updated one.

Q. Oh, I thought you said you had it there.

A. No, no. My records, that I brought with me, I do not have an updated reliance. I have what you provided today, or whoever provided it. I don't know

Page 23

who provided it.

Q. Okay. So --

MR. CARTMELL: Does Exhibit --

THE WITNESS: Exhibit 2.

MR. CARTMELL: -- 2 have an updated reliance list?

MS. GEIST: It does not. Exhibit 2 is the originally provided expert report with the original reliance list.

BY THE WITNESS:

A. Then I do not have an updated reliance list.

Q. Okay. I misunderstood. I thought you said you had it there.

A. No. I'm sorry. I have my bibliography, but the reliance list -- well, which is part of the reliance list, obviously. But I did not bring the Bates numbers, depositions, exhibits, I did not bring an updated one of those.

Q. Okay. Well, let me ask you this. So, in your original Materials Relied list, there is a list of depositions that you're looking at there, right, Doctor?

A. That is correct.

Q. And it doesn't have with that a list of any exhibits to those depositions, correct?

A. Well, it has exhibits listed down below from Dr. Ross's deposition. But Dr. Ross -- that appears

Page 24

that's the only exhibits that are listed with this one.

Q. Did you ask for any of the exhibits that were marked at all of the other depositions?

A. Oh, I can't, I mean --

MR. CARTMELL: Well, again, I think I told you, for your clarification, that I think not including the exhibits in the first round was the lawyers' fault. That's my understanding.

BY MS. GEIST:

Q. Okay. So let me just ask you. When you originally formed your opinions in this case and provided your expert report, had you already had all of the exhibits to the depositions that are listed here?

A. Yes. I had what is listed here; and in the various different depositions, I would have used those.

Q. And it appears to me, from looking at the updated reliance list, Dr. Elliott, that you also looked at one additional transcript from the time you provided your expert report; is that right?

A. I don't understand what you mean a transcript. You mean a deposition?

Q. Yeah. Well, let me -- let me ask it differently. After you reviewed the depositions that are listed on your reliance list, did you ask to see any other depositions that were taken in the Bard

Page 25

litigation?

A. I did ask. I can't recall who it was. Because as I read depositions, in there they will make reference to other depositions. I would be able to think of a specific example of that one back to SDMS (sic) issue where they made a reference to a Chevron or Phillips employee. I wanted to see what his comments were, so I requested that.

Q. Okay. That employee's name is Frank. And I'll --

A. Zakrzewski, or something like that, yeah.

Q. Right, Z-A-K-R-Z-E-W-S-K-I. So that was on your updated reliance list?

A. Correct. That was just an example of it. Again, I can't -- because, you know, these are hundreds of pages long. There's references around, so I'll ask for clarification. I might not ask for the entire document. I might say, Pertaining to this specific, what was said?

Q. So when you asked for the deposition of the Phillips Sumika representative on the MSDS issue, did you review the entire transcript?

A. No. I asked -- I wanted to know the specific comments that were made, so I did not review the entire document.

Page 26

Q. So did you get the entire document or did you just get excerpts?
A. I got excerpts.
Q. Did you ask to see the entire document?
A. I don't recall what I asked for. I had a specific question about a specific reference from a deposition, so I wanted to know specifically what was going on. So I didn't ask for the entire document, I don't recall.
Q. Do you know what pages you got from that deposition?
A. No, I do not.
Q. You have your laptop here with you, right?
A. Yes, I do.
Q. Do you have it there on your laptop?
A. I would have, probably, an e-mail, an internal correspondence with the lawyers, but then it wouldn't have any -- it would have, again, the specifics. I don't know if it would have a date on there or anything.
Q. So you don't have the excerpts of the --
A. Oh, I have the excerpts. I have the expert was -- here, I can provide that for you, if you'd like that.
Q. Well, I'm trying to find out, Doctor, what portions of that Phillips Sumika witness testimony you

Page 27

reviewed.
A. Okay. I'll give it to you. Zakrzewski, Z-A-K-R-Z-E-W-S-K-I, deposition. I don't have the date, but page No. 204 and 205.
Q. So you reviewed two pages of the deposition from the Phillips Sumika representative on the MSDS topic?
A. That is correct.
Q. Do you think that was enough for you to get the full picture of what that company representative had to say on the issue?
A. I don't know. If you have more information on it, I would like to hear it.
MR. CARTMELL: Just so you know, he was provided the whole deposition.
MS. GEIST: Well, I -- I'm going to object to any testimony by counsel. I mean, he's already said he looked at two pages.
MR. CARTMELL: Do you want him to be accurate on what he was provided? He can tell you what he's reviewed; but, I mean, I think you would want it to be accurate on what he was provided.
I'm just telling you he was given the entire deposition. He may not remember it, but he was.

Page 28

BY MS. GEIST:
Q. Did you only review the two pages of the deposition?
A. That's all I recall reviewing.
Q. And then, Doctor, the -- what I'll call the third part of your reliance list relates to literature, articles, or I think you called it your bibliography, right?
A. Correct.
Q. And when you say bibliography -- and you have a hard copy there in front of you?
A. That's correct, yes.
Q. -- we're talking about the same thing, right?
A. The same -- same thing. That is correct. I just called it a bibliography, though.
Q. All right. And you already told me that, for each and every article cited here, there are a total of 509?
A. Correct.
Q. And you read all of them?
A. I read most every bit of all of them.
Q. Every page of every article?
A. I said most every bit of all of them.
Q. Do you know which articles you skimmed and

Page 29

which you thoroughly reviewed?
A. I do not recall.
Q. Do you know what percentage of the articles listed here you reviewed in their entirety versus skimming?
A. As I said, I'm a reviewer for 15 journals. Two years in a row I was best reviewer for Journal of Urology and Female Urology section. So I do this for a living. And so I read almost everything of almost all of the articles. All of them I can't recall the specifics.
Q. So almost everything of almost all of the articles; is that your answer?
A. That is correct.
Q. Doctor, we'll obviously talk a lot today about your opinions that you've rendered in this litigation on behalf the plaintiffs, but let me ask you a couple of questions about what you're not going to opine about. Okay?
A. Okay.
Q. You're not offering any opinions relating to Bard's products as being less safe or more risky than any other manufacturer's product used to treat pelvic organ prolapse; is that correct?
MR. CARTMELL: Object to the form.

Page 30

BY THE WITNESS:
A. I'd have to kind of, maybe, have you rephrase the question. I don't quite understand.
Q. Sure.
A. Please just ask it again.
Q. Sure. Are you offering any opinions that Bard's Avaulta products are less safe or more risky than any other manufacturer's mesh product used to treat pelvic organ prolapse?
MR. CARTMELL: Same objection.
BY THE WITNESS:
A. Okay. I would have to say that I would offer an opinion that it would be at a higher risk for further complications based upon the product design and implantation.
Q. So that's not in your expert report anywhere.
MR. CARTMELL: Object to the form.
BY MS. GEIST:
Q. Do you have any statements, in your expert report, that Bard's Avaulta products are more risky or less safe than another manufacturer's pelvic organ prolapse product?
A. Not directly. Indirectly it is.
Q. So what's your opinion on that?
A. That they're at higher risk based upon the

Page 31

design of the product. And it's in my expert report, specifically in -- starting on page 21 where I talk about the arms of the Avaulta Solo and the Avaulta Plus being unreasonably dense. That is one section. Those arms are more dense than the other available products.
Number two, on the mesh design where collagen is implanted, that makes it a different product than the other ones. It makes it unique. So I discuss it in there. I have what's on page 23, using the porcine collagen greater inflammatory response.
Off the top of my head, those are the two issues that would say, I would say, that it is at higher risk for complications than the other available products.
Q. So when you talk about the other available products, what products are you talking about specifically?
A. The -- well, to the best of my knowledge, none of them are available anymore. But AMS Apogee/Perigee, Boston Scientific Pinnacle, the Ethicon's Prolift Anterior/Posterior Total.
Q. So it's your opinion that the Bard Avaulta products are more risky and less safe than the AMS, Boston Scientific, and Ethicon products?
A. That's what I've indicated in my report, yes.

Page 32

Q. And the basis for that opinion is, one, that the Bard products have four arms; is that right?
A. No. Again, that's a summary of what is in my report. The report gives it more generally -- more specifically. But the arms are more dense, there is no plastic covering over the arms causing sawing is another one that's in there, and then the porcine collagen. And off the top of my head, without reviewing it page by page, those are the ones that come to mind.
Q. Well, Doctor, you just said it's in my report. But there's nowhere in your report, is there, where you provide the opinion that Bard's products, Bard's Avaulta products, are more risky or less safe than the AMS, Boston Scientific, and Ethicon's pelvic organ prolapse products?
A. Well --
Q. It's nowhere in the report, correct?
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. That's because I'm not providing an opinion today on those other products. We're not doing a comparative. We're just doing --
Q. Well, that's what I'm asking you.
A. Well, number one, you interrupted me.
Q. I apologize. I don't mean to do that.

Page 33

A. I was still talking.
Q. Hold on. Hold on. We can't talk over one another. You're a fast talker, Doctor, and sometimes so am I. So I don't mean to be rude. I do apologize. I do want to let you finish your testimony, and I will try my best not to step on your words. So go ahead.
A. Can you read back where I was?
Q. Well, why don't we just start with a new question. I think it's the same question.
What I was saying to you, Doctor, is, let me make sure you understand the process. Okay? In litigation when somebody is an expert witness, they give what's called the expert report. And you've been an expert witness before, correct?
A. Yes.
Q. You're sort of familiar with this process?
A. On the periphery. I'm not a lawyer.
Q. Understood. But us lawyers have certain rules, and we are entitled to notice about the issues and the opinions that an expert is going to give at a trial in the case. Do you understand that?
A. Yes.
Q. And the report --
MR. CARTMELL: I would just object to the form.

Page 34

BY MS. GEIST:
Q. The report is supposed to contain all of the opinions that an expert is going to talk about at a trial. Okay. That's sort of the rules of the game, if you will. Do you understand that?
MR. CARTMELL: Object to the form. And I'll move to strike the legal statements of counsel. Go ahead.
BY MS. GEIST:
Q. So that's what -- that's what I'm getting at, Doctor. I'm trying to understand, if you hold any opinions that the Bard Avaulta products are more risky or less safe than the AMS, Boston Scientific, and Ethicon products also used to repair pelvic organ prolapse.
MR. CARTMELL: Okay. Is that a question?
MS. GEIST: Yes.
MR. CARTMELL: Okay. You've asked him that question and he's answered it. So objection, asked and answered.
BY MS. GEIST:
Q. So do you have an opinion, Doctor, that you plan on giving in this litigation that the Bard Avaulta products are more risky or less safe than the AMS, Boston Scientific, and Ethicon products?
MR. CARTMELL: Same objection. Asked and answered.

Page 35

BY THE WITNESS:
A. If I am asked that question, I will render that opinion. If I'm not asked that question, I won't.
MR. CARTMELL: And you just asked him that.
BY MS. GEIST:
Q. So what I'm trying to find out now, okay, because this wasn't in your report -- it's not in your report, right, these statements you're telling me now?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. I've already answered that. It is -- it is stated in there. It's not stated in the exact words you're talking about. But we're saying in there, specifically, on page 23, Avaulta Plus porcine collagen caused even greater response than synthetic polypropylene mesh alone.
Okay. That is an opinion against Avaulta that -- Avaulta Plus that causes higher complications than the other polypropylene meshes. So I have stated it. I just didn't use the exact words you want me to use.
Q. Well, I don't want you to use any words, Doctor. I'm trying to understand exactly what your testimony would be at the trial. There is nowhere in your report that says Bard's products are less safe or

Page 36

more risky than the AMS, Boston Scientific, and Ethicon products? There's nowhere in the report that says that. There's no comparative analysis, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. If you want -- I disagree. I wholeheartedly disagree.
Q. Well, show me in your report where --
A. You interrupted me again when you said you weren't.
Q. I thought you were finished.
MR. CARTMELL: Just let him finish.
BY THE WITNESS:
A. I'm right in the middle of a sentence.
MR. CARTMELL: Just let him finish. Go ahead.
BY THE WITNESS:
A. Avaulta Plus porcine causes even greater response, inflammatory response, than the synthetic polypropylene mesh alone; AMS, synthetic mesh alone; Ethicon, synthetic mesh alone; Boston Scientific, synthetic mesh alone. That is a statement saying there is even greater inflammatory response.
Q. Are you finished?
A. Yes.
Q. So that relates only to the Avaulta Plus

Page 37

product, correct, the collagen polypropylene product?
A. Correct. As stated there, yes.
Q. What sort of comparative analysis have you done, Doctor, comparing Bard's Avaulta Plus porcine collagen product to other products?
A. I compare it to the available literature out there; specifically, with the Prolift product because there is the most literature on that. Unfortunately, there is very, very little Avaulta data out there. But I also compare it to the available literature and experience dealing with porcine and collagen when placed transvaginally or in the abdominal wall for that matter, too.
Q. So can you point me to any study where the Avaulta Plus collagen polypropylene product was compared to another mesh product?
A. Paraiso, et al., Rectocele Repair: A Randomized Trial of Three Surgical Techniques Including Graft Augmentation, from 2006, where there they had a collagen graft with an increased failure rate that it was theorized due to impaired healing.
Q. And which products were involved in that study?
A. That was a collagen graft. I would have to go back and look at the exact study to find out what

that -- what were involved.

Q. Well, was it the Avaulta product?

A. Again, I would have to -- I would have to go back and look at that study.

Q. You can't tell me sitting here now?

A. I cannot tell you sitting here now, no.

Q. I'm looking for any study, Doctor, where the Avaulta product was specifically compared to the AMS, Boston Scientific, or Ethicon product and they did a comparative analysis of incident rates.

A. When I searched PubMed, which is 24 million articles, and searched Avaulta, I don't believe I was able to find any study where that was done, which would have been a very nice study to have been done, to see if it was a better product.

Q. Is there any study out there that looked at the comparative incident rates between the Bard products and these other products that you mentioned to me that you say are less safe or more risky?

A. I do not recall, in those specific words, a randomized controlled trial of the other products with the Avaulta Plus.

Q. So, in other words, Doctor, there is no study that has compared the incident rates, for example, of erosion, pain, or dyspareunia, of the Avaulta products

to other mesh products; is that true?

A. I am unaware, as we sit here now, of any randomized, controlled, non-industry-sponsored trial comparing those two products head to head.

Q. How about any trial? Forget about randomized or industry sponsored. How about any trial? Can you point me to any study, whatsoever, that did this type of comparative analysis, the Bard product versus the other products, and concluded that the Bard products were less safe or more risky? Can you point me to one single solitary study?

A. The studies I can quote to you are not a head-to-head comparison. They are either comparing the native tissue, native repairs, the Avaulta Plus, or just Avaulta Plus, period. You then have to look at the body of knowledge out there and the data and could then compare those to the erosion rate, the infection rate, the pain rate, delayed healing rate, the other products with the Avaulta Plus.

Q. All right. So let me ask it a different way. Since there's no -- we know there's no head-to-head study that looked at the Bard products versus these other products that you say are more safe or less risky. There's no study out there. This is just your opinion unsupported by any single article or medical literature,

correct?

MR. CARTMELL: Okay. Object to the form. That's argumentative and completely misstates his prior testimony related to the literature on that.

BY MS. GEIST:

Q. Correct?

MR. CARTMELL: Same objection.

BY THE WITNESS:

A. Incorrect. I disagree completely. I can point you to many studies talking about the Avaulta Plus or anything containing collagen transvaginal showing a higher impaired healing rate.

Q. That's not my question, Doctor. My question is this. I asked you to tell me about a single solitary study, industry-sponsored or otherwise, that looked at the comparative incident rates of adverse events between the Avaulta Plus products and other mesh manufacturers' products and concluded that the Avaulta products were less safe or more risky. And you can't point me to a single solitary study that does that; isn't that true?

MR. CARTMELL: Okay. Object to the form. Just for clarification, are you talking about a head-to-head RCT Avaulta Plus versus another product?

MS. GEIST: I think my question is clear, and you have made your objection. It doesn't have to be a

randomized controlled trial. Any study, any.

MR. CARTMELL: Well, okay, it's been asked and answered.

BY THE WITNESS:

A. I think I can do better than that and compare it to the literally hundreds of pages of articles out there on other products and then comparing it to the very few on Avaulta Plus. To isolate it to just one randomized controlled trial, it would be helpful, but it does not exclude the knowledge gathered from the other studies.

Q. Doctor, you're not answering my question. You know, I've asked it now three different times. And if you're having a hard time understanding me, then let me know.

MR. CARTMELL: We're not --

BY MS. GEIST:

Q. I want to know --

MR. CARTMELL: Melissa --

BY MS. GEIST:

Q. -- and I'd like to move on the articles --

MR. CARTMELL: Listen -- no, no, no.

MS. GEIST: You're interrupting me. You're interrupting me.

MR. CARTMELL: I am interrupting you because here

Page 42

is the problem. Your statements by counsel, okay, that he's not answering your question, when you've asked multiple different questions, you keep saying it's the same one, but it's not, is unfair to the witness and harassing. All right. So he's answered your question multiple times. And I'll let you ask it one more time and then we're moving on. I'm not going to let him answer it.

BY MS. GEIST:

Q. So my question is, Doctor, you can't point me to a single study, whether it's industry-sponsored or otherwise, a single study that looked at the Avaulta Plus products compared to other mesh manufacturer products and concluded that the Avaulta products were more risky or less safe; isn't that true?

MR. CARTMELL: Objection. Asked and answered.

BY THE WITNESS:

A. I can quote to you studies -- if you limit me as far as limiting all of the available knowledge in that fashion, then it would probably be difficult, but that's --

Q. Well, Doctor --

A. You're interrupting me again.

MR. CARTMELL: Let him finish.

BY MS. GEIST:

Page 43

Q. I would like to move on. It's a yes or no. Is there a study or not?

MR. CARTMELL: You want it to be a yes or no, but what -- he needs to answer your question and then you can move to strike it. Okay. Go ahead.

BY MS. GEIST:

Q. Doctor, I would like a yes or no. If you can point me to a study, let's talk about the study. If there is no such study, would you please just tell me there is no such study and then we can move on.

MR. CARTMELL: Objection. Asked and answered. You can answer it again.

BY THE WITNESS:

A. There will be no yes-or-no answer. It's far more complicated than that. To limit the fund of knowledge out there to a yes or no is wrong and shortchanges the available knowledge. I can point you to studies -- I have them here -- showing that Avaulta Plus has higher inflammatory reaction, delayed healing. I can point you to other studies with polypropylene mesh that has a less reaction.

Q. You're not going to answer my question, Doctor?

MR. CARTMELL: Object to the form. It's argumentative.

Page 44

BY MS. GEIST:

Q. You can't point me to a single study, can you?

MR. CARTMELL: Object to the form. It's been asked and answered. He's just answered it. No more questions like that, please.

BY MS. GEIST:

Q. Well, I'm going to move on. I think it's pretty clear, from the record, you can't point me to a single study.

MR. CARTMELL: Object to the statement of counsel and move to strike it.

BY MS. GEIST:

Q. How about -- how about this one? When we're talking about adverse events resulting from a complication from mesh, generally speaking, we're talking about things like erosion, inflammatory response, pain, and dyspareunia; fair summary? It's not supposed to be a complete summary, but those are some of the more frequent adverse events we're talking about, correct?

A. Incorrect. I take care of patients daily with a myriad of complications. To even limit one time the number of complications these patients experience and the life-changing effects is unfair to them. So I'll disagree with your comment.

Page 45

Q. All right. I'm trying to summarize, Doctor, the adverse events or potential complications that a patient may experience after having mesh implanted for pelvic organ prolapse. I was trying to give you a summary.

So my question is this, is there any study that looked at the incident rates of dyspareunia for patients experiencing that problem after having implanted -- after having been implanted with an Avaulta product versus a Boston Scientific or Ethicon product?

MR. CARTMELL: Object and move to strike the statement of counsel before the question.

BY THE WITNESS:

A. I'm sorry. You're asking for a study comparing Avaulta versus native tissues or are you going back to the Avaulta versus the other mesh products?

Q. I'm going by adverse events. So let me go -- let me ask it again.

Is there any study that looked at the adverse event of dyspareunia and concluded that there was a higher incident rate of dyspareunia with the Bard products compared to the AMS, Boston Scientific, and Ethicon products?

A. You're going back to the same question we already went over and over and over.

Page 46

Q. I'm asking specifically about dyspareunia. Is there any study that looked at that particular adverse event, potential complication resulting from a mesh implant, and concluded that there was a higher incident rate of dyspareunia with the Bard products compared to other mesh manufacturers' products?

A. I have studies stating that the Bard product has higher complications than the native tissues.

Q. I'm not talking about native tissues.

A. And then limiting it to one of those randomized control looking at dyspareunia alone, I don't have that data with me.

Q. Is there any data that looked at dyspareunia and said there is a higher incident rate with the Bard products compared to other mesh manufacturers' products?

A. Well, I would have to say there probably is not because, if you had that data, Bard would have provided it for me. And this would be a very good format, because you asked if I had been provided all of the information available. I did the PubMed research. I am taking care of patients on a daily basis. I'm going to meetings and I'm asking for all of the data available. That would have been a very nice piece of data to have provided to me.

Q. So you don't -- you don't have that data,

Page 47

Doctor, and you've never seen that data, correct?

A. Well, I have also had the opportunity of reviewing the Bard depositions, and nowhere did they present this data being available either.

Q. You don't have that data, Doctor, and you've never seen that data, correct?

A. I've already answered this.

Q. Okay. That's fine. How about things like pelvic pain? Pelvic pain is a known complication that a woman may experience after having a mesh implant, correct?

A. Correct.

Q. Any study out there that has looked at the incident rates of pelvic pain associated with the Avaulta products and concluded that the incident rates were greater with the Avaulta products compared to any other mesh manufacturers' products?

A. No. I can quote to you many studies showing that the incidence of pelvic pain and dyspareunia is higher. But when you limit it to comparing it to the other products, we would -- there is no -- we can't have a quality head-to-head comparison. We have to go based upon the studies that are available.

Q. Okay. So the answer to my question is correct? No study that's looked at the Bard product,

Page 48

compared it to other mesh manufacturers' product and said that there is an incident -- greater incident rate of pain associated with the Bard products?

MR. CARTMELL: Objection. Asked and answered.

BY MS. GEIST:

Q. Correct?

MR. CARTMELL: You can answer it again.

BY THE WITNESS:

A. Okay. Limiting it, in the severe fashion that you're doing, I do not know of, right now, any study that compared the head-to-head comparison of these, any randomized, controlled, industry-sponsored, et cetera.

Q. The same thing with erosion rates, Doctor? There is no study out there or article that concluded that the Bard products have more incident rates of erosion compared to other manufacturers' mesh products used for pelvic organ prolapse?

A. There are plenty of studies out there showing it has a higher extrusion rate. You said erosion, which would be the incorrect word, but extrusion rate compared to the native tissues. I am unaware, sitting here now, of any randomized controlled trial stating it has a higher rate compared to other mesh products.

Q. Do you consider yourself to be an expert on Bard's Avaulta products, Doctor?

Page 49

A. Yes, I do.

Q. How does a doctor like yourself, who is a practicing urologist, how should a doctor like yourself go about becoming an expert in a medical device product?

MR. CARTMELL: I object to the form.

BY THE WITNESS:

A. You have to look at the totality of training: six years of pelvic surgery training; one year of advanced surgical training in pelvic floor dysfunction, including surgery; and then becoming certified in female pelvic medicine and reconstructive surgery, which is approved by the American Board of GYN and American Board of Urology; and then practicing for 15 years at a higher level, a high-volume tertiary care center.

Q. And how about, Doctor, if you want to become an expert on this specific product, what should you do to do that?

A. Be aware of the FDA regulations involved in submission and clearance of a product, be involved looking at the warnings, the regulations, the labels of that product, be involved in teaching residents or staff how to implant or how to more -- more appropriately for me taking care of the complications, also being daily taking care of patients that deal with this. That provides expertise that most don't have.

Page 50

Q. So you should become familiar with how to implant the actual product. Is that what you said?
A. I didn't say that. You need to be -- you need to be familiar with how the product goes in, you know, reviewing of videos, surgical videos, seminars at our national/international meetings, and then be familiar with transvaginal surgery.
Q. Reviewing a video relating to the implantation of a medical device is not the same thing as actually doing it?
A. No. And I've also been involved in cadaveric labs as far as implantation of meshes, polypropylene, pelvic organ prolapse meshes.
Q. You agree with me, though, that reviewing a video instructing how to implant an Avaulta product is not the same thing as actually implanting an Avaulta product?
A. Well, I said I did it in cadaverics, also.
Q. How about in a live patient?
A. Well, if you -- if you limit me to implantation only in living human beings, I have never once implanted transvaginally pelvic organ prolapse meshes by choice.
Q. So you never once implanted the Bard products for which you're giving an opinion, correct?

Page 51

A. I have never implanted the Bard mesh; however, I have significant experience taking out the Bard mesh.
Q. You've never implanted any type of pelvic organ prolapse kit from any manufacturer, true?
A. Well, asking the way you did now, that is incorrect.
Q. So which pelvic organ prolapse kit have you actually implanted in your career?
A. That would be the AMS Interpro.
Q. And when did you do that?
A. The last one would have been about a week or two -- no, three weeks ago, something like that.
Q. And that's a transvaginal procedure?
A. No.
Q. What type of procedure is that?
A. A robotic sacrocolpopexy.
Q. Is that -- is that product manufactured using polypropylene mesh?
A. Yes.
Q. How about reviewing public literature relating specifically to the product in which you're giving an opinion. Would it be a good idea to do that?
A. By public literature, you mean, like, patient brochures? I just want clarification.
Q. No. I mean, any literature or articles

Page 52

published relating to that particular product. Do you agree with me it would be a good idea to review all of the literature out there on that particular product?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. I only just -- I just want to make sure I'm clear on what you're asking as far as the medical literature, medical manuscripts, abstract presentations at meetings, if that's what you're asking, then, by all means, it is essential as one of the components of gaining experience with the product.
Q. It's essential to read all of the public literature about that product?
MR. CARTMELL: Object to form.
BY MS. GEIST:
Q. Is that what you're telling me?
A. I would never use the word all. I would say you better have a good grasp of the available trends of thought on a product.
Q. Well, when you say a good grasp, what do you mean by that?
A. A good grasp is going to be relative. Okay? I'm at a high-volume institution, a tertiary care center, so I'm taking care of these patients on a daily basis, so -- and with national and international

Page 53

meetings, I just got back from a meeting in Stockholm dealing with mesh problems, okay. So my grasp of it is a daily interaction.
If you're talking about an individual out in private practice, in the middle of somewhere else, that's going to take a little bit more work to become involved, to have a good grasp of available knowledge. So, again, that's a relative statement.
Q. Okay. Let me try and bring it back, Doctor, because what I'm talking about is, you told me you believe you're an expert on the Bard Avaulta product, correct?
A. I am an expert on the Avaulta product, yes.
Q. Okay. So my question is, is it a good idea to read all of the literature, the published literature, about the actual product in which you're claiming to be an expert?
MR. CARTMELL: Object to the form. It's vague and ambiguous.
BY THE WITNESS:
A. I can state, without any shadow of a doubt, absolutely I have read all of the available documents that I know of, medical literature published and some in abstract form, on the Avaulta products.
Q. How many published articles are there relating

Page 54

to the Avaulta products specifically, do you know?
A. Yes.
MR. CARTMELL: Object to the form. Go ahead.
BY THE WITNESS:
A. I can state of what I did on my search. This was not provided to me by counsel. This is my search that I came up with 17 articles.
Q. And are all of those listed on your reliance list?
A. Yes. And some of those will be from meetings where the general public won't have access to those because they're abstract forms that I have access to.
Q. How about reviewing the regulatory submissions for the clearance to market a medical device? Is that a good idea to review that in order to become an expert on that device?
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. I think you have to have a good working knowledge of the requirements, regulations, the warnings, and the labels for a product.
Q. I appreciate that answer, Doctor. But my question is, is it a good idea to read the regulatory submission to the FDA in order to become an expert about that medical device?

Page 55

MR. CARTMELL: Object to the form. Asked and answered. He just answered that exact question.
MS. GEIST: No, he didn't.
MR. CARTMELL: You can answer it again. Yes, he did.
MS. GEIST: No, he didn't.
MR. CARTMELL: Well, see, what you want to do is you want to --
MS. GEIST: No, no, no.
MR. CARTMELL: No, no.
MS. GEIST: We're not -- hold on. Hold on. Wait for the record.
MR. CARTMELL: Step out of the room.
THE WITNESS: I'll step out.
MR. CARTMELL: Go ahead and step out. Go ahead and step out.
(Exit the witness.)
MS. GEIST: We're not going to proceed today with speaking objections.
MR. CARTMELL: We're not going to proceed like you're doing right now. Okay.
MS. GEIST: Wait. Hold on. You have to let me finish.
MR. CARTMELL: No. I'm talking right now. Go ahead. We are not going to proceed today --

Page 56

MS. GEIST: All right. You go first and then I will go.
MR. CARTMELL: We're not going to proceed today where you ask a question and he answers it and you don't like his answer because it's not your yes or no, you know, in a question that can't be answered yes or no. So you do your little harassment statement like, Doctor, you haven't answered my question. I'm going to answer (sic) it again in hopes that he gives you exactly the answer you want. We're not going to do that for hour after hour after hour.
We've been going for an hour now and you've done it about 30 percent of the time. So I want to make the record clear that you can ask him a question. I'm fine with it. If he gives you an answer, then you need to move on. If he doesn't answer it, I'm fine with you re-asking it. But when he does, in fairness to the witness, don't try to harass him into giving an answer that you think is right even though he's answered it already. That's my record.
MS. GEIST: So my record is this, the objections during this type of deposition, like any other deposition taken according to the Federal Rules, are objections to form, not speaking objections. We've been going, I guess, about an hour and you have made multiple

Page 57

speaking objections, which are against the rules. So I'd ask you to stop doing it.
MR. CARTMELL: Okay.
MS. GEIST: Make your objections to form for the record. The doctor -- and just for the -- just for the record about this last question, he did not answer my question.
MR. KUNTZ: Let's go back and read that.
MS. GEIST: I asked him --
MR. KUNTZ: He absolutely did. Let's go -- let's go back and look at it.
MS. GEIST: You're interrupting me.
MR. CARTMELL: No.
MR. KUNTZ: Because you're wrong. Pull it up and look at it while he's out of the room. You're not even close he answered it.
MR. CARTMELL: Right.
MR. KUNTZ: You're not even close.
MS. GEIST: You're interrupting me. I asked him specifically about whether he should review, somebody who is claiming to be an expert on the product, whether they should review the regulatory submissions for that product. And he gave me a whole answer about you should be familiar with regulatory rules and everything else. The answer (sic) was, did he review the regulatory

Page 58

submission for this product or not? He hasn't answered that question.
MR. KUNTZ: And he said, yes, three questions before that.
MS. GEIST: No, he didn't.
MR. CARTMELL: You didn't ask him if he reviewed the regulatory submission for this product.
MS. GEIST: I said, would it be a good idea --
MR. CARTMELL: Hold on.
MS. GEIST: -- to review the regulatory submission for the product in which you're claiming to be an expert.
MR. CARTMELL: Okay. And his response was you need to have a working knowledge of the regulatory requirements for the product. He answered your question.
MS. GEIST: No, that's not the -- let --
MR. CARTMELL: If you --
MS. GEIST: -- answer --
MR. CARTMELL: Don't interrupt me.
MS. GEIST: You guys are interrupting me. It's like a tag team here.
MR. CARTMELL: If you then ask him, Well, did you review the regulatory submission for this product, Doctor --

Page 59

MS. GEIST: I will.
MR. CARTMELL: -- then that would be a different question. But he answered your first question.
MS. GEIST: No, he didn't.
MR. CARTMELL: And you wanted him to say, yes, and he told you that it was -- it would be required to have a working knowledge. Now you're entitled to then explore that, Melissa. I'm fine with that. But, you know, the problem is you ask these questions that are not precise, he answers them part- -- you know, particularly the way he can based on your question that's not precise, and you're offended by that and you ask the exact same question.
That's the problem I have with it. That's it. Now he's out of the room. That's why he's out of the room, because I didn't want to do this, all of this speaking stuff, in front of him. And I will continue to send him out of the room when we get to situations where you're just not being fair to the witness. That's the only reason I want to make it clear on the record is my speaking objections are going to be when he's out of the room, but I am going to continue to do them as long as you're unfair to the witness.
MS. GEIST: Well, I appreciate your comments. You've been making plenty of speaking objections while

Page 60

he's been in this room. This is the first time he's been out of the room. So we'll just continue it and see how it goes.
MR. CARTMELL: Okay. You can come in.
(Enter the witness.)
MR. CARTMELL: Can we, for the record, read your last question and his response?
MS. GEIST: I agree with that.
MR. CARTMELL: Okay.
(Record read as requested.)
MS. GEIST: Right.
MR. CARTMELL: Thank you.
BY MS. GEIST:
Q. And I appreciate that, Doctor. But my question is, should you review the regulatory submission -- the submission, not the regulations that you talked about and the other things you talked about -- in order to become an expert on a particular medical device, would it be a good idea to review the submission to FDA for that product to be cleared?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Specifically, the 510(k) submission you're referring to?
Q. Yes.

Page 61

A. Yes.
Q. And did you do that in this case?
A. Yes, all 506 pages of it.
Q. Thank you. Is that 510(k) submission on your reliance list, Doctor?
A. I'd have to look at the reliance list. I'm not sure.
Q. But it's your testimony that you reviewed the 510(k) submission for the Avaulta products in its entirety?
MR. CARTMELL: Object. Asked and answered.
BY MS. GEIST:
Q. I'm just trying to understand your testimony.
A. Okay. The document, as I recall, was, roughly, 506 pages. I may be off on that, plus or minus 10 or 20 here and there. I went through and read over almost every single page of that. I scanned every single page. Some of them were duplicates. Some it was regulatory data. So, yes, to answer your question.
Q. Thank you. Doctor, I know we just went off -- well, we didn't go off the record, but you left the room for a little bit on a break. Are you okay to keep going right now, or do you need a --
A. No. No. Keep going.
Q. -- bio break or anything? Okay. Great.

Page 62

Let me have you look at your deposition notice for a second, Doctor, which we've marked as Exhibit 1 to your deposition. Have you seen this before --

A. Yes.

Q. -- Dr. Elliott?

A. Yes.

Q. Okay. It asks you to bring a number of things with you here to your deposition. Do you see that?

A. Yes.

Q. They're listed on Exhibit A?

A. Correct.

Q. The first thing is a copy of your CV. Do you see that, Doctor?

A. Yes. Yes.

Q. That's contained as part of your expert report, correct?

A. Yes.

Q. Is that an up-to-date version of your curriculum vitae and bibliography?

A. It appears to be within the past month or so, so it would be fairly accurate.

Q. Do you need to add anything or provide any addendum to that CV sitting here now?

A. As I sit here now quickly going over it, I don't think anything significant needs to be added.

Page 63

I've given some recent talks at Minnesota's Urology's Society. That might not be on here, but that would be not pertaining to mesh products. The most important one is I sit on the education committee for Society of Urodynamics and Female Urology, and I need to make sure that's on here.

Q. Okay. If it's not, as long as you just testified to that, that's fine.

A. Yeah.

Q. Anything else?

A. And that would be -- and then papers, it appears to be accurate.

Q. Referring to your papers for a minute, do you have any particular area of research that you concentrate on?

A. The pelvis.

Q. The pelvis, in general?

A. Well, I mean, as far as research and incontinence, pelvic organ prolapse is where I focus on.

Q. If someone were to ask you, well, you know, Doctor, what are you best known for, what's your claim to fame, what would you say?

A. Probably dealing with mesh organ complications, dealing with complications, the surgical correction of those, male incontinence, being the first

Page 64

in the world to perform a robotic sacrocolpopexy and writing on that.

Q. The robotic-assisted laparoscopic sacrocolpopexy?

A. Correct.

Q. That's one of the prime areas of your research; fair to say?

A. I focus quite a bit on that, yeah.

Q. How many times have you published on the area of mesh complications?

A. One that I know of, that I can think of off the top of my head, and then another one is submitted but it has not been published yet.

Q. And where on your CV is the one publication that you've done relating to mesh complications?

A. Well, as far as specific -- excuse me. Let me go to my -- this is not in the format I'm usually used to looking at it.

Q. Take your time.

A. Speaking of mesh complications and papers that involve mesh complications, that would be No. 37, Robotics and Laparoscopy for Vaginal Prolapse and Incontinence.

Q. That paper has to do with mesh complications?

A. Correct.

Page 65

Q. Okay. And what else?

A. Then --

Q. Is there anything else?

A. Yes. And then No. 43, Shimko, Umbreit -- oh, it's my paper. I'm the senior author -- Long-Term Outcomes of Robotic-Assisted Laparoscopic Sacrocolpopexy. And then --

Q. I'm sorry. That paper also has to do with complications associated with mesh implantation?

A. Absolutely.

Q. And what else?

A. And I'm trying to get to the first article we wrote on this. I will get there in just one second. Here we go. Number 24, which I am the senior author, Robotic-Assisted Laparoscopic Sacrocolpopexy With Treatment of Vaginal Vault Prolapse.

Q. All three of those articles focus primarily on your work and research relating to robotic-assisted laparoscopic sacrocolpopexy, correct?

A. What I've mentioned so far has been, but I haven't gone through my CV completely.

Q. Okay.

A. Okay. Number 25 is, Time-Dependent Variations in Biochemical Properties of Cadaveric, Porcine Dermis, Porcine Small Intestine, and Polypropylene Mesh, and

Page 66

Autologous Fascia in a Rabbit Model. Number, Gynecologic Use of Robotic-Assisted Laparoscopic Sacrocolpopexy For the Treatment of High Vaginal Vault Prolapse.

Q. Those -- those two articles, 25 and 26, have to do with mesh explant procedures?

A. Mesh complications, mesh inflammatory process. Number 27, where I am the senior author, time -- time-dependent variations in inflammation and scar formation in six different pubovaginal sling materials in a rabbit model, which polypropylene was one of those.

Q. These three studies you just cited to me, 25, 26, and 27, these were all animal studies, correct?

A. No. Incorrect. One of those was human. 24 was human.

Q. Sorry. I was talking about 25, 26, and 27?

A. Okay. 25, no. 26 is human. 28, Current Status of Robotics in Female Urology and Gynecology, focused on the complications and the management of complications.

Q. For mesh?

A. For mesh. Number 30, Long-Term Results of Robotic-Assisted Laparoscopic Sacrocolpopexy For the Treatment of High-Grade Vaginal Vault Prolapse. Number -- do you want me to go through the whole list,

Page 67

because it keeps going here.

Q. Well, I'm sort of -- I'm sort of bewildered, Doctor, because I read all of these articles and they all deal with robotic-assisted laparoscopic sacrocolpopexy primarily. There may be a line or two in here about mesh complications. But I think it's a stretch to say any of these articles deal with mesh complications; do you disagree?

MR. CARTMELL: Object. It's argumentative.

BY THE WITNESS:

A. I --

Q. I'm not trying to be argumentative. I'm asking if you disagree.

A. I completely disagree. Is it mesh? Yes. Is it for vaginal prolapse? Yes. Is there complications? Yes. So, unequivocally, yes, this is dealing with complications.

Q. So maybe my question wasn't precise. Do any of these articles deal with mesh complications resulting from a transvaginal implant of polypropylene mesh?

A. Yes. Number 54, does risk -- repeat risk -- excuse me. Risk of Repeat Anti-Incontinence Surgery Following Sling Release, a review of 93 patients, which the majority of those were mesh obstructions and treatments.

Page 68

Q. And that was -- that article relates to mesh implanted to treat stress urinary incontinence, right?

A. Correct.

Q. Or the sling procedure, in other words?

A. Sling is a generic term for it; but, by and large, you're correct, yes.

Q. Okay. And I am using a generic term. Have you published, Doctor, in the area of mesh complications resulting from transvaginal implant of mesh for the purpose of repairing pelvic organ prolapse?

A. We have submitted manuscripts dealing with laser resection of pelvic -- of pelvic organ erosion from meshes involving not just incontinence procedures, but also pelvic organ prolapse. And I have been invited to speak at the SUFU meeting in February speaking with laser management of these complications. And that paper has also been submitted to the American Urologic Association meeting in May this year.

Q. So you have a pretty extensive publication list on your CV. You agree with me on that, Doctor, I assume? We're not going to argue about that?

A. I work hard on it.

Q. Yeah. And you've done some pretty good and cutting-edge work in the areas of robotic-assisted laparoscopic sacrocolpopexy. Fair to say?

Page 69

A. We were the first in the world to do it and publish on it, yes.

Q. Yep. But you don't have a single article yet published relating to mesh complications resulting from the use of transvaginal mesh for pelvic organ prolapse; is that true?

A. Not yet. But we've spoken on it in national and international meetings and have manuscripts submitted.

Q. Okay.

A. But you are -- you are correct, limited to publications, no, I do not.

Q. And you told me you have something in submission?

A. Correct.

Q. Does it have a title?

A. Well, yes, it does have a title. I can't quote it exactly. It will be Holmium Laser Management of Transvaginal Mesh Erosion.

Q. I'm sorry. What did -- what laser management? Can you say that for me?

A. A Holmium, H-O-L-I-U-M (sic), Laser Management of Transvaginal Mesh Erosion. So that includes in there the pelvic organ prolapse erosions into the -- into the bladder, urethra.

Q. What is holium (sic) laser management?
A. Holmium, it's just a type of laser. It's a specific product of laser. There's different types of lasers, green light laser, all of these different types of lasers. This happens to be one specific type of laser that we have found works quite well on dealing with some of these mesh problems.
Q. Are you the lead author on the paper?
A. I am the senior author.
Q. Is there a difference?
A. Lead author -- well, it depends how we were defining it.
Q. I don't know. How are you defining it? Senior meaning old or --
A. We have first author -- you have first author, second author, third author, fourth author, or however many authors there are, and then a lead or senior author. Lead or senior one means they're the boss. First author is the one who does the most as far as the data gathering or work on it.
Q. And what -- what journal or journals have you submitted the article to?
A. The Journal of Urology.
Q. And who else was involved in the research on this article?

A. Well, we have a resident involved with it.
Q. Is it you and a resident?
A. Yeah. Myself and a resident, yeah. But there has been multiple residents over the years who have gathered data and things like that.
Q. And, in a nutshell, what's the summary and conclusions of the paper?
A. It is meant to address the problem of the mesh erosions, which early on in my career, we were -- I was doing a lot of major transabdominal procedures to get the mesh out. It was a very morbid or bloody and painful procedure. A colleague of mine uses holmium lasers to break apart stones, and we did some research and found that it works on polypropylene.
So we had a woman who originally came in to us with a mesh that went through the urethra, which is very difficult to deal with, to take out. It's scarred in like crazy. So we decided to try it with her consent. That we -- it may or may not work. But if it works, it will save her major surgery. And so we were able to, with the laser, go in and cut the mesh off as it went through and through the urethra.
Q. So is this a one-patient case study?
A. No. That was a patient that prompted the dealing with it. But, again, the traditional way of

doing that is transvaginal and the urethra is shredded apart. The women is usually or can be totally incontinent the rest of her life. So we wanted to try a different way. So that was the impetus, the initial patient one. And then since then I've seen a fair number of these. We're up to about 15 or 20 of these types of --
Q. Sorry. Let me interrupt you purposefully. When you said 15 or 20, so you've performed the holmium laser procedure on 15 or 20 patients?
A. Correct.
Q. Okay. Sorry. Go ahead.
A. But we submit the paper and then we continued to gather data, so I can never remember what the numbers are because, again, we continue to add. So it's roughly 20, and that's involving mainly -- well, it is essentially just the bladder and urethral injuries.
Q. We're talking about women who have experienced visceral erosion?
A. Well, into the bladder. The gynecologists at my institution will deal with the perforations -- well, actually, I'm sorry. I take that back. There was one woman who had a rectal perforation, so we dealt with that one, too. So -- but, mainly, mine our bladder and urethra. The gynecologists at my institution are

dealing with the ones involving other organs. We kind of agreed to divide up the -- so we can have more expertise in dealing with this.
Q. So what was the outcome of using the holmium -- holmium laser to excise the mesh?
A. We have, roughly, a 75 percent success with one treatment. Unfortunately, the ones who come back with a recurrent erosion, it requires multiple treatments to try and get those fixed and some of them we can't get fixed. I just saw one of them back last week and she has, now, a recurrence of her erosion into the bladder. The problem has continued to get worse.
Q. Is this the only pending publication or manuscript submitted for publication relating to mesh extraction?
A. I believe so, yes.
Q. And is the laser procedure, I assume, a minimally invasive procedure?
A. Well, minimally invasive is a relative term, also. It is less invasive than doing this with an incision. It is -- there are significant risks when we do this because any woman -- any woman who has an erosion, whether it be urethra or vagina into the bladder, the tissues are thin. And so, as we resect this, we can get into the vagina through and through and

Page 74

cause a fistula. So there are major risks with it. So I would be very hesitant to call it -- it's relative. It's relative to open surgery, it is minimally invasive. Relative to doing a bladder biopsy, it's significantly invasive. That's not to be evasive in the answer. It's just that it's subjective.

Q. No. Understood. Okay. Doctor, going back, now, to Exhibit 1, which is your notice of deposition --

A. Yes.

Q. -- it asks you also for a list of all cases in which you have, during the past four years, served as an expert essentially?

A. Correct.

Q. So, in the past four years, have you served as an expert other than here in the Bard pelvic mesh litigation?

A. Yes.

Q. And can you let me know about those circumstances, please?

A. Yes. What are we, 2014? So 2011 or '12, with Ethicon on the Prolift, I wrote up an expert report; however, I did not go to trial, or however you phrase -- however you phrase that.

Q. Have you ever testified at trial as an expert witness?

Page 75

A. One time.

Q. And when was that?

A. That was not related to mesh. That was a patent infringement case of generic medical devices versus Coloplast for their transobturator mesh sling. Well, I guess it was a mesh. It was a mesh sling. But that was patent infringement. It had nothing to do with complications. It was patent infringement. And that took place in Tacoma District Court, I believe.

Q. How many times have you given a deposition as an expert witness?

A. Three.

Q. And were those all on behalf of the plaintiffs in a litigation?

A. Correct.

Q. And were those all against mesh manufacturers?

A. Manufacturer, Ethicon.

Q. So, prior to this, you gave three depositions on behalf of plaintiffs and against Ethicon in a mesh proceeding?

A. I'm going to have to take that back. There was a deposition in November of '11 or '12, and then there was a deposition a few weeks ago. Both of those were with Ethicon and then you. So actually it's three total.

Page 76

Q. When did you start getting involved working as an expert for plaintiffs in the mesh litigation; do you remember?

A. I believe -- well, actually, I do know. It was in September or so of 2011.

Q. And were you retained by plaintiff's counsel at that time in cases pending against Ethicon?

A. I don't know the legal nomenclature. I mean, they -- I was contacted. They wanted to know my opinion on subjects, I told them, and then we went from there. So, as far as retained, I don't know that term.

Q. Okay. I apologize for that. Let me just ask it this way. You started working with plaintiff's counsel back in September of 2011 in litigation or cases pending against Ethicon; is that a fair summary?

A. Correct.

Q. And who did you start working with?

A. Mr. Ben Anderson.

Q. And what firm is he with, do you know?

A. Anderson Law Firm in Cleveland.

Q. Had you had any prior experience with that law firm?

A. None.

Q. How about for the --

VIDEO TECHNICIAN: Can you repeat that? Sorry.

Page 77

BY THE WITNESS:

A. Just the Anderson Law Firm in Cleveland, and I had had no prior contact with them.

Q. And how about for the Bard litigation? When did you start working for plaintiffs in the Bard litigation as an expert?

A. Summer of 2014.

Q. So pretty recent?

A. Well, June or so, so five months ago.

Q. And who approached you to work on this litigation?

A. Mr. Anderson.

Q. The same guy?

A. Correct.

Q. Did you bring, as requested in your deposition notice, any invoices or records relating to your compensation as an expert in the litigation?

A. I don't have those with me, no.

Q. What did you bring with you today, Doctor, in response to the notice? We already -- you have your bibliography, right?

A. I have paper copies of my expert report, my bibliography, then the case-specific reports. And then I have electronic copies of -- as far as everything that's on my reliance list, and then most manuscripts.

Page 78

Not all, but most manuscripts.
Q. Okay. So sort of in front of you you have paper copies of your reports, your bibliography, and your reliance list. Everything else is accessible on your laptop?
A. Correct. And, to be technical, in front of me includes Dropbox. I have everything.
(Brief interruption.)
MR. CARTMELL: Uh-ooh.
MS. GEIST: How about can we take a five-minute bio break?
MR. CARTMELL: Sure.
MS. GEIST: Thanks.
VIDEO TECHNICIAN: We're off the record. The time is 10:51 a.m.
(A recess was had.)
VIDEO TECHNICIAN: We're back on the record. The time is 11:06 a.m.
BY MS. GEIST:
Q. Doctor, referring again to the notice of deposition --
VIDEO TECHNICIAN: Counsel, sorry, I can barely hear you.
MS. GEIST: I'm sorry. I forgot to put on my microphone.

Page 79

BY MS. GEIST:
Q. Doctor, you got your microphone on?
A. (No verbal response.)
Q. All right. I'm the only one who forgot.
Doctor, referring, again, to your notice of deposition, if you flip with me to the second page, it looks like, of the notice, it asks you to bring with you correspondence or e-mails between you and plaintiffs' lawyers that relate to your compensation. Did you bring any of that with you here today?
A. I don't have any e-mails related to compensation. I guess I don't -- what do you mean?
Q. So are you being compensated for being an expert witness, I assume?
A. Yes, I am.
Q. You're being paid for your time?
A. Yes.
Q. Have you submitted any invoices so far for work on the cases?
A. Yes.
Q. How many invoices?
A. Well, it started in the summer, this summer. I submit them at the end of the month. So I don't know exactly what month I submitted it, but there would be three or four invoices.

Page 80

Q. Did you tell me earlier you started working on the litigation in or about June of 2014; is that right?
A. More or less. It was during the summer. I don't recall exactly.
Q. Okay. That's fine. And you invoice after every 30 days?
A. At the end of the month, correct.
Q. So there would be invoices from approximately July, August, September, October?
A. Correct.
Q. You don't have copies of those with you today?
A. I do not, no.
Q. Can you tell me how much time you spent working on the litigation so far?
A. I don't recall an exact number, no.
Q. How about an approximation?
A. Greater than a hundred.
Q. Greater than a hundred hours?
A. Correct.
Q. So are we talking a thousand hours or somewhere between a hundred and 200 hours?
A. Again, this is pure speculation. I don't know. I can't recall the exact numbers. It would be greater than a hundred, less than two or 300.
Q. All right. So somewhere between 100 to 300

Page 81

hours; is that a fair summary?
A. Probably closer to 200 hours.
Q. Okay. So somewhere between 100 to 200 hours?
A. Correct.
Q. And that time was spent reviewing all of those 500-plus articles that are on your bibliography?
A. That's --
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. That's part of what I was doing.
Q. And what else?
A. Reviewing patient records, reviewing internal documents.
Q. So does the 100 to 200 hours include the work you did to form your opinions contained in your generic report as well as your case-specific reports?
A. Correct.
Q. Okay. Did you break your invoices out separately, invoices for the specific cases versus the invoices for the generic opinions?
A. I submit to Mr. Anderson's office my hours spent. I don't know if it gets broken down after that.
Q. So do you have detail about what you did in those hours, or is it just an invoice that says I spent 50 hours?

A. No. It -- no, it will have a daily breakdown of each day, deposition review, manuscript review.

MS. GEIST: Can we go off the record a second?

VIDEO TECHNICIAN: We're off the record. The time is 11:10 a.m.

(A recess was had.)

VIDEO TECHNICIAN: We're back on the record. The time is 11:11 a.m.

BY MS. GEIST:

Q. So, Doctor, just going back to your invoices to plaintiffs' counsel, so there is sort of a narrative for your time spent?

A. There is a brief description of what activities; deposition review, manuscript review, patient record review.

MS. GEIST: Okay. And, Counsel, I'll just ask that those be provided to us since they were included in the notice of deposition and they're not here today.

MR. CARTMELL: Okay. We'll track them down.

MS. GEIST: Thank you.

BY MS. GEIST:

Q. How much money have you made so far on the litigation, Doctor?

A. Because I don't know the number of hours, I can't tell you how much I've earned. So I don't have

even a ballpark figure.

Q. Are you being paid as the invoices go in?

A. Yeah. I get paid a month to two months after the invoice is submitted.

Q. And you don't know how much you've made so far?

A. I don't keep record, no.

Q. Do you have a ballpark?

A. No, I don't, because I -- I don't even know the number of hours I've spent, so I can't even extrapolate from that.

Q. So you can't even give me an estimation of how much money you've made and how much you've been compensated for your work on behalf of plaintiffs in this litigation?

A. Again, I can't. The invoices will spell it out exactly, but I don't keep records like that.

Q. Well, Is it more than $100,000?

A. Again, I don't -- I don't know. I know that I've spent more than a hundred hours working on it. But, again, I don't know how much. I don't keep -- have any way of accurate records pertaining to that.

Q. So let me just look at your fee schedule, and that was part of your expert report, right?

A. Correct.

Q. And it just says fee schedule is 700 an hour, right?

A. Correct.

Q. Is the 700-dollar-an-hour fee for anything you do in order to prepare your expert report? In other words, does that cover review of medical records, review of literature, research?

A. Correct.

Q. Do you have a different hourly rate for testimony?

A. No, 700 flat fee.

Q. So, sitting here today, however long we're here together today, it's 700 an hour?

A. Correct.

Q. You don't have a flat fee for an appearance at a deposition or anything like that?

A. No, I do not.

Q. How about trial testimony?

A. 700 flat fee.

Q. How about travel?

A. $700 an hour.

Q. So it's $700 an hour whether you're testifying, traveling, or reviewing medical records?

A. Correct.

Q. Was that the same rate that you charged

plaintiffs' counsel when you were working as an expert in the Ethicon litigation?

A. Correct. It's always been 700 hours -- $700 an hour.

Q. Can you tell me how much you were compensated for your work as an expert witness against Ethicon in their pelvic mesh litigation?

A. Same answer, I don't know the number of hours. It would be more than Bard, but -- because it was a lot longer process, but I don't know the amount.

Q. Are we coming anywhere near a million dollars?

MR. CARTMELL: Object to form.

BY THE WITNESS:

A. I wouldn't think so, no; but, again, I don't keep records like that.

Q. So you don't have any sense at all, even to give me a ballpark estimate, of how much money you've made as an expert witness on behalf of plaintiffs in the pelvic mesh litigation?

A. No. It's been going on three years, and I don't keep records.

Q. Can you tell me what percentage of your annual income is derived from work as a plaintiff's expert in the pelvic mesh litigation?

A. That would probably vary from year to year, a

Page 86

third, maybe.
Q. Meaning?
A. Again, I don't even know how much I get on my salary from my day job.
Q. When you say your day job, you're talking about your job as an associate professor of urology?
A. Correct.
Q. At Mayo?
A. Correct. I don't have records. It's a bank deposit and I don't even look at it. I don't know what my benefits are. I know what my retirement is, but I don't know what my daily salary is or monthly salary.
Q. You don't know how much money you get from Mayo Clinic as an associate professor?
A. No.
Q. Really?
A. It's -- the data is retrievable. I don't worry about it.
Q. What about, a third of your income over the last three years has been from work as an expert witness on behalf of plaintiffs; is that right?
MR. CARTMELL: Object to the form.
BY MS. GEIST:
Q. Well, is that what you just told me?

Page 87

A. That would be rough. You know, going back to 2011, it's probably going to be closer to 25 percent. But, again, that's a ballpark figure, because I don't -- that's not something I keep track of.
Q. Dr. Elliott, in reaching your opinions that you've rendered in this litigation, did you rely on any facts or data that were provided to you by counsel for plaintiffs?
MR. CARTMELL: Object to the form. I don't understand the question.
BY THE WITNESS:
A. I mean, I thought that's data they had provided me. They provided me with what's on the reliance list as far as internal documents.
Q. Did you rely on any summaries or information provided to you prepared by counsel?
A. Well, they didn't provide me any summaries. They provided me documents.
Q. Did -- did any of your opinions that you've reached in this litigation, were any of them based on assumptions that were provided to you by counsel?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. No. I had strong opinions regarding transvaginal mesh starting back prior to 2011, starting

Page 88

back in 2005, really. And so what they provided me would augment or increase my knowledge and understanding, but it didn't alter.
Q. You already were sort of out there as a well-known doctor speaking against transvaginal mesh; is that fair to say?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. I was -- I was one of those speaking out against meshes, that's correct, the anti-mesh group.
Q. You're one of leaders of the anti-mesh group?
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. Well, I don't know how you justify it. I may not quantify if I'm a leader or not. I've made --
Q. Well, you're one of the -- I'm sorry. Go ahead.
A. I've made public statements.
Q. So you're one of the most outspoken physicians in terms of the anti-mesh group?
MR. CARTMELL: Object to the form.
BY MS. GEIST:
Q. Is that fair to say?
A. No. I wouldn't say I'm one of the most. I think there's some others out there who have been much

Page 89

louder in speaking against meshes.
Q. Who has been much louder than you?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Shlomo Raz at UCLA, Philippe Zimmern at UT Southwestern, Louis Wahl at St. Louis, Ostergard. I don't know where he's at, California somewhere. But I'm not denying it. I've been anti-mesh from the beginning. I'm not saying I'm not, but I'm not the only one out there.
Q. Did you review any of the expert reports provided from some of the other doctors rendering reports on behalf of the plaintiffs?
A. I'd have to look in the reliance list for all that I've reviewed. I have reviewed expert reports. I can't recall all of the ones I have reviewed.
Q. Well, for this particular litigation, your opinions here, did you rely on any of the other reports provided on behalf of plaintiffs by other experts?
A. It depends on how you're defining rely. I'm looking at them with an open mind seeing what they have to say and if it's consistent or inconsistent with my opinions. So, yes, I've looked at the materials expert's report. I don't recall his name. I'm not very good with names. So, again, my reliance report would

Page 90

have that on there. I don't know if we have an updated copy of that. That might be nice, too.

Q. You understand there's a separate materials or biomaterials expert who has provided opinions in the litigation, correct?

A. Correct. Yes.

Q. And you're not a biomaterials expert, correct?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Well, I wouldn't say that's correct. I have deal -- I deal with meshes. I deal with mesh complications. I've done research on meshes. I deal with the complications and transvaginal management of those things. I have two animal studies -- three animal studies, excuse me. I take that back. Two animal studies dealing with meshes. So I have basic science and human research on this.

So I am a materials expert. Am I a Ph.D. or an engineer in biomaterials, no. But I do consider myself, from the urologic-GYN perspective, a biomaterials expert.

Q. So that's a little different than what you said when you were deposed in the Ethicon proceeding; do you remember that?

A. I don't recall.

Page 91

Q. Do you remember admitting, in that deposition, that you were not a biomaterials expert?

A. I would have to --

MR. CARTMELL: Object to form.

BY THE WITNESS:

A. I would have to see what I said. If you have that, I would like to see that.

Q. You know what, Doctor, I can't find it right this minute, but I don't want to waste time. So I'll pull it up and look again.

But do you recall giving a deposition in the litigation against Ethicon here at Wexler Wallace's office a couple months ago on September 13th, 2014?

A. Yeah. I remember giving a deposition, yeah.

Q. Do you remember that? And do you remember being asked about whether or not you were a biomaterials expert?

A. I don't recall that specific question.

Q. But it's your testimony here today that you are a biomaterials expert?

MR. CARTMELL: Objection. Asked and answered. He just answered that same question.

BY THE WITNESS:

A. I agree with exactly what I just said this time with those qualifiers.

Page 92

Q. So do you have a background in polymer science?

A. Well, I've taken organic chemistry and physics, so I do have a background in dealing with those products.

Q. Do you consider yourself an expert in polymer science?

A. As it pertains to the transvaginal application and the complications, I have a better working knowledge than the average with it.

Q. No. That wasn't my question. Are you an expert in polymer science?

A. Define --

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Define expert then.

Q. So do you have any degrees in either polymer science or biomaterials?

A. With those qualifiers, no, I do not have an advanced degree in polymer science.

Q. Do you have any particular education in polymer science or biomaterials?

A. I have a significant amount of education pertaining to those issues.

Q. Tell me about that.

Page 93

A. Okay. As far as dealing with meshes and their complications, reviews of the medical literature, both basic science and human research in vivo and in vitro. I would have to say in reviewing the internal documents, both with Bard and also with Ethicon.

Q. So other than being engaged in explant procedures and reviewing documents, do you have any particular training or education in the area of biomaterials or polymer science?

A. Oh, yeah. I've written two papers on that specifically dealing with the polypropylene meshes in the rabbit model, dealing with the forces involved with fracturing, the inflammation, dealing with the pathologists and engineers.

Q. Did -- and it's those two papers on which you rely for your expertise on polymer science and biomaterials?

A. Well, that's two of the ones that I rely upon, yeah, but that was pretty extensive work done.

Q. Have you ever been qualified as a biomaterials or polymer science expert?

A. I guess I don't understand that question. Again, I am not a Ph.D. in the subject. I'm not a Ph.D. in the subject. I don't carry that, but I am an expert dealing with the ramifications when implanted in the

Page 94

female body.
Q. Do -- have you ever been qualified by a judge at a trial as an expert in polymer science or biomaterials?
A. I have no way of answering. I don't know if I have it or have not.
Q. Do you hold yourself out to your colleagues as an expert in polymer science or biomaterials?
A. In biomaterials and mesh and mesh complications, I do hold myself out as an expert in it and they also hold me out as an expert by inviting me to speak this year at the National Female Urology Meeting on mesh complications and management of them, and that's all dealing with the biomaterials and complications.
Q. Did -- have you conducted any type of laboratory or other type of testing on the Avaulta polypropylene mesh products?
A. Not specific on the Avaulta polypropylene. I've done it on collagen, but not on polypropylene.
Q. You've never tested the Avaulta products, correct?
A. If you're talking -- you're meaning a basic science research? I guess, I don't know what you mean by that. Clarify what you mean.
Q. Well, did you -- have you done -- have you

Page 95

published any paper relating to the Avaulta products?
A. Okay. Specifically with the Avaulta product, yeah, our laser -- our laser resection paper is going to have an Avaulta product in it.
Q. Have -- you've never done a study on Avaulta products, though, have you?
A. Not limiting it to just Avaulta products, no.
Q. Well, what studies have you done that involved Avaulta products?
A. Well, I'm talking about the laser resection paper.
Q. That's the one that you've submitted for publication?
A. Correct.
Q. It hasn't been approved or accepted for publication yet, correct?
A. Correct.
Q. And the extent of the discussion of the Avaulta products in that paper relate to the explant procedures you did -- you did using a laser?
A. Correct.
Q. And how many women, again, were involved in that paper?
A. 15 to 20.
Q. And how many of the 15 to 20 women had Avaulta

Page 96

products that were explanted?
A. For that paper, roughly, a third.
Q. And how do you know that it was the Avaulta products you were involved in explanting using the laser?
A. Because prior to me seeing any patient, I have to have the outside records, outside implantation records.
Q. So you have them for all of the third of the 15 to 20 women?
A. Correct. I have them for all of the women and a third of them, roughly, were Avaulta products.
Q. Other than this experience with the Avaulta products, have you done any testing or analysis on the Avaulta products?
A. No. I've reviewed the testing of others.
MR. CARTMELL: Sorry.
BY MS. GEIST:
Q. You haven't actually conducted any tests on the Avaulta products yourself, correct?
A. Other than what I mentioned as far as the study, I personally, to the best of my knowledge, have not done a basic science study on it like you mentioned.
Q. Okay. And we already talked before you've never implanted an Avaulta product, right?

Page 97

A. Correct.
Q. Do you know any of the plaintiffs' experts in this litigation?
A. I don't know who the plaintiffs' experts are other than, I believe, Dr. Wilkes. I think I saw his name, but I don't know him. But I don't know who their other experts are.
Q. Did -- other than plaintiffs' counsel, did you talk to any other physicians about your opinions in this case?
A. No.
Q. Did you meet with any of the other plaintiffs' experts and talk about your opinions in this case?
A. I don't even know who the other plaintiffs' experts are.
Q. You understand that you're not being put forward as a biomaterials expert here, correct?
MR. CARTMELL: Well, I object to the extent I don't think that's a correct statement. I mean --
MS. GEIST: Well, you told me before --
MR. CARTMELL: -- he -- he's clearly, in his report, giving biomaterials expert opinions. So I'm going to instruct him not to answer that question. That's based on a fact that's not true.

BY MS. GEIST:

Q. You understand there is a separate biomaterials-designated expert on behalf of plaintiffs in this litigation as you've told me before, correct?

A. I believe Dr. Wilkes is a biomaterials expert; but, again, I don't know.

Q. Didn't you tell me that you reviewed some of the other expert reports and you reviewed the report of the biomaterials expert, whoever that may be?

A. No. For clarification with that, I reviewed Wilkes' report. I don't know if I've reviewed any others in the process of this.

Q. Did you review a report from a biomaterials expert?

A. Well, I don't know what Dr. Wilkes' role is. So I would have to look up and see what his role is. That report I reviewed.

Q. And what did that report talk about?

A. It talked about the meshes, the complications, the pore sizes, the inflammation, collagen, interplay.

Q. From a materials standpoint?

A. That's what I'm saying. I don't know. I also talk about the same things.

Q. In any of the reports that you reviewed, did you disagree with any of the conclusions reached by any

of the other experts?

A. Again, the only report that I recall reviewing was Wilkes'. I don't recall reviewing the others. I may have. And with Mr. Wilkes or Dr. Wilkes -- again, I don't know what his title is -- I had no objection with what he had to say.

Q. You're board-certified, Doctor, in urology, correct?

A. Correct.

Q. And female pelvic medicine and reconstructive surgery?

A. Subspecialized in female pelvic mesh and reconstructive surgery by the Board of GYN and the Board of Urology.

Q. So are you board-certified in female pelvic medicine reconstructive surgery?

A. Correct. They don't really call it -- you would be technically correct. They don't really call it that. You're board-certified in urology or GYN. You then do subspecialty certification in female pelvic mesh and reconstructive surgery. That is a new development in this field in the past five to eight years. So those of us who did -- did residency and fellowship prior to the starting of that -- that subspecialty, then we had to go back and get further testing.

Q. Didn't they offer board certification in female pelvic medicine and reconstructive surgery beginning in 2013?

A. Yeah. That's when I took the exam. Again, I just don't know if you --

Q. So -- all right. So I don't understand why my question is difficult. So you took the exam in 2013?

A. And passed. I mean, technically, you're right as far as calling it board certification. We don't go around saying we're board-certified in this. We're board-certified in urology. We're board-certified in GYN or dermatology, whatever. There is subspecialty certification that is approved by the board. So if we want to just for -- I'm not trying to be difficult, but you can call it board-certified by urology and GYN in female pelvic mesh and reconstructive surgery.

Q. So you're not a board-certified urogynecologist, correct?

A. Correct. I am not.

Q. That's a subspecialty of obstetrics and gynecology?

A. Correct.

Q. What's the difference between a urogynecologist and a urologist?

A. Well, a urogynecologist and a urologist is not

a fair comparison. I am a female urologist, okay. That's the comparison you want because both of us have advanced training in the female pelvis, and in urology we also have it in the male pelvis, too. So there's very -- once you have passed that female pelvic mesh and reconstructive certificate, you have that certificate, in the eyes of the boards, you are identical.

Q. That's your opinion?

A. That's the boards' opinion, the boards of urology and the boards of GYN.

Q. You told me earlier that, in this study that's pending approval relating to the laser that you used to explant mesh, that about a third of the women had been implanted with Avaulta products; is that right?

A. That's a rough estimate, yes.

Q. Okay. So, I guess, five to six women based on the total women involved in the study; is that --

A. Well, it's 15 to 20 patients.

Q. Right. So I'm saying five to six --

A. So five to seven.

Q. Five to six, five to seven?

A. Five to seven -- yeah, five to six, that's fair.

Q. That's fine. We don't have to argue about those numbers.

Page 102

What has been the totality of your experience in explanting mesh from women who were implanted with the Bard Avaulta products?

A. I'm sorry, the -- from this --

Q. How many?

A. From this study?

Q. Yeah. No, no, no. Not just the study.

A. Oh.

Q. So how many. Because you told --

A. Sure.

Q. -- we've already talked about the fact that you've never implanted an Avaulta product yourself, correct?

A. Correct. Yep.

Q. But part of the basis for your statement that you're an expert on the Avaulta product is based on your experience explanting the product, true?

A. That's only partially true. That is part of my experience.

Q. And that's what I meant to say.

A. Okay.

Q. So if I misspoke, that's fine. But part of the basis for you saying that you're an expert on the Avaulta product is due to your experience explanting the product, correct?

Page 103

A. Correct. That is one segment of my experience.

Q. Got it. How many times?

A. I see, in a given week, four to five, six patients with mesh complications that started roughly in 2007 or thereabouts, and then -- it started off slow and then it's increased. So I can't give you how many numbers, but then not all of those, in fact, the minority, are going to surgery because what I am seeing them mainly for is pelvic pain. And so I'm operating on only a minority of those individuals.

So if you look at just the surgical, that's going to be a smaller number. If you look at the -- you're just looking at the numerator. You have to look at the denominator, which is four to five patients a week. Let's just round it up to five patients a week. It's going to be, roughly, 60 -- let's see -- 60 percent, roughly, are going to be AMS products, and then it's -- excuse me, 40 percent are AMS products, and, roughly, 30, 30 are, excuse me, Ethicon and Bard, and then I will see a smattering of the other percentages of the other products. The Boston Scientific we don't see very many. Also, the Cook product, I see those, also. So hundreds would be the answer to that.

Q. So how do you know that? What's the basis for

Page 104

that statement?

A. Because I keep track. I keep records of these things. And I keep track of who we're seeing on my clinic schedule, and I also have operative notes on essentially every single patient that comes through. I demand it before I see them.

Q. So that's getting more to my question. For every patient that's referred to the Mayo Clinic that you see, do you determine which manufacturer's mesh product they had implanted?

A. Well, I determine it because we review the medical records.

Q. Are they all required to come with the medical records?

A. Before. They're supposed to have it before they show up. And if they show up without it, then before we do anything we need to have them fax us the records.

Q. And did you perform some sort of analysis or compilation to determine that 30 percent of the patients you've seen have had one of the Bard products implanted?

A. Yeah. That's -- that's going to be a rough estimate because, also, we're going back to 2007, which was a smaller number of individuals, but we're keeping records then. And so I'm extrapolating that, but that

Page 105

is going to be a rough and fair estimate. AMS Apogee/Perigee is going to be the predominant product that I see. As I mentioned, they're roughly 40 percent. That's because AMS is based 100 miles north of Rochester. So we get a lot more patients who have that implanted.

Q. So from 2007 to 2014, has it always been about the same number of referrals per week? You told me four to six or rounded to five patients per week?

A. Start off slow starting in, roughly, 2007. Again, that's an estimate. That's looking back. We started seeing an uptick in patients. And then, as time progressed, then we started seeing more and more and more. And then in 2011, after that FDA release, that's when we really saw the increase. So, now, the four to five or four to six per week is current for the past three years. I can't speak with any accuracy going back to 2010 and prior.

Q. What do you think was the reason why, in the last three years, you started getting more referrals?

A. Very clear, because patients tell me, knowledge that this is occurring to other people besides themselves. That's the most common comment I get.

Q. And where do they get that knowledge?

A. Because they -- they read about and heard

Page 106

about the FDA warning, and then they are sitting out thinking they're alone, and then, all of a sudden, they find out there's more people who have the same problem.

Q. Well, they're coming to you because they see lawyer advertisements on TV, right?

MR. CARTMELL: Object to the form.

BY MS. GEIST:

Q. Isn't that how they get the knowledge?

MR. CARTMELL: Object to the form. He's already answered that question.

BY MS. GEIST:

Q. Can you answer my question, Doctor?

A. Yeah. I can't speak to where they're getting the information, but they're getting the information.

Q. Do you ask them?

A. I usually do not.

Q. You just suddenly since 2011, since there has been a lot of advertising on television, you've had a huge uptick in plaintiffs coming or patients coming with mesh-related complications?

MR. CARTMELL: Object to the form. I think he just told you about the FDA 2011 statement.

MS. GEIST: You've got to stop with the statements.

MR. CARTMELL: Well, when you totally leave out what he --

Page 107

MS. GEIST: Let the witness --

MR. CARTMELL: Hold on. When you totally leave out what he just told you, change the question to include something else, that's unfair. So, in that circumstance, I'm not going to let you do it.

MS. GEIST: You've got to make an objection to form; and, otherwise, you have to stop.

BY THE WITNESS:

A. Can you repeat the question? I'm sorry. Oh, I know your question. I can answer it without it.

No. That's actually quite ridiculous to think that they're doing it based upon lawyers. We're seeing time progressing, so we're now having time for the complications to happen. Patients are becoming aware of it and, more importantly, I think doctors are becoming aware of it. Doctors did not know this was happening to the extent it was happening. And they're realizing that being a situation. We're also starting to write papers on it. So the knowledge is coming to the forefront.

Q. How -- you told me, I think, before that the women coming to the Mayo Clinic that you've seen specifically do not all require some sort of excision or explant procedure; is that right?

A. Well, to say require, that's not the right word. That means I can't fix them --

Page 108

Q. All right.

A. -- with surgery. I don't think surgery will fix it. Because when we have an individual who has devastating pelvic pain all over, okay, they can't sit, they can't walk, they can't lie down, and we do an exam and everything hurts, I do not -- I do not recommend surgery on them because I don't think it will fix it. I think it will make them worse.

Q. How many of the patients that are referred to the Mayo Clinic that you've been treating, Doctor, how many of them are actually undergoing an explant or excision procedure?

A. A percentage. Let's say -- let's say we see five a week times, what, 42 weeks a year. That's going to be difficult. That's too much math. A rough estimate would be about 20 percent of the individuals I see I feel are candidates for surgery. I have become more conservative in my surgeries. They have to meet very specific criteria because, otherwise, I don't think I do them any good.

My GYN colleagues in the past have been much more aggressive than I am doing transabdominal repairs, and they have some success and have a lot of others that are not. Philippe Zimmerman (sic), a good friend of mine at UT Southwestern, was showing something like 35

Page 109

to 40 percent persistent pain after removal of pelvic meshes, and so I am very careful in who I select.

Q. So how many times have you done an explant or excision procedure since 2007 that involved a patient who had a Bard Align -- pardon me, a Bard Avaulta product implanted?

A. Well, that would be more starting with Bard starting in 2008, 2009, because we didn't see them initially. The same thing with Prolift. We didn't see those in 2005. We saw them in 2007.

Again, we're going to look at it, if you do the math, we're roughly five patients a week, 30 percent of those are going to be a Bard product, and I'm going to be operating on 25 percent of those. So, again, we'd have to do the math of whatever those numbers are. But, again, that is not -- that's not counting all of the ones I see that I don't operate on. So just looking at the surgical numbers is unrealistic as far as the true nature of the extent of the problem.

Q. Well, I'm trying to understand, if you can tell me sitting here today, how many times you've explanted mesh from a patient that you can tell me was from one of the Bard products?

MR. CARTMELL: You mean just --

Page 110

BY MS. GEIST:
Q. To the best of his --
MR. CARTMELL: -- Solo or Plus.
MS. GEIST: To the best of his estimate, right.
MR. CARTMELL: Do you mean any Bard product?
MS. GEIST: Well, we're talking about the Avaulta products.
BY MS. GEIST:
Q. And I can see, Doctor, you're sitting there doing some math calculations; is that right?
A. 310, estimate.
Q. That's based on the mouth -- math calculations you just did now?
A. Correct. Roughly, five per week times, roughly, 45 weeks per year, times, roughly, five or six years, and then, roughly, that's how many we're seeing as far as Avaulta products. And then, roughly, as far as surgeries, it comes out to, roughly, 312 surgeries if you want exact -- or if you want an educated, accurate answer.
Q. So my question was, had you ever gone back before doing what you just did now here, some quick math based on assumptions, did you ever go back and take a look and say, Let me see if I can determine how many explant procedures I did that involved the Bard Avaulta

Page 111

products?
A. Well, yeah. We keep -- as I mentioned, we didn't initially keep track. As the mesh problems started to manifest themselves, we were all caught off -- unaware because we were unfamiliar with this type of thing coming along, so we didn't initially keep track. And then prior to 2011 is when we started doing this math, and that's when we started realizing we've got a big problem here. So, yeah, that was -- again, that was before any of this litigation process was going.
Q. Right. But that's my question. Before you sat here today and did that quick math that you just did for me, did you ever go back, in preparation for this deposition or in your expert report, and determine how many times you've done an explant or excision procedure that involved the Bard Avaulta product?
A. Well, that's what I -- that's what I just told you. I said that, roughly, 30 percent of the patients that I see are Avaulta.
Q. Right. But you told me -- you also told me that the 30 percent of the patients you see that are Avaulta product users do not all go through an explant or excision procedure, right?
A. Correct.

Page 112

Q. All right. So what percentage of the 30 percent actually have an explant or excision of the mesh?
A. That's what I said, 25 percent of those.
Q. So 25 percent of the 30 percent that you see have some sort of explant or excision procedure?
A. Correct, that I feel meet, that their pain is isolated. Just like the woman I saw two weeks ago, the pain was isolated to the arms of the mesh in the transobturator region. She had pinpoint pain. I could touch it. I could feel a knot in there consistent with scarring and inflammation. Those are the individuals that will repair. I feel that can go for it for pain. But that's not also counting the extrusions. See, we see -- we have just many, many extrusions.
Q. Is the -- is the 25 percent your best guesstimate sitting here today?
A. Yes, and that's a fairly accurate estimate.
Q. What's --
A. Because, you know, we keep --
Q. -- it based on?
A. Our medical records, because I have a track of every single patient that I see, and then we have it broken down. I get -- every year I get a computer printout of every single patient and tallying those

Page 113

patients up. I also get a record of every surgery that I do and tally them up. So I can't give you exact numbers, but I can give you very accurate numbers.
Q. And -- and I assume you would agree with me, Doctor, that you don't have a denominator, if you will, for the women who were implanted with the Avaulta product, correct?
MR. CARTMELL: Object to the form.
BY MS. GEIST:
Q. You don't know, in other words, how many women were implanted with the Avaulta product during this time period that you were excising or extracting mesh, correct?
A. In my review of the Avaulta records, I have not seen a specific number. In my review of other companies' records, they have always refused to give those numbers out. So I would actually like to see. That would be very helpful for me to see because usually they won't tell me. They'll say we don't know.
Q. So the answer to my question is, you don't know what the denominator is, so you can't determine what the incidence rate is, for example, for women requiring an explant or excision procedure after being implanted with the Avaulta product?
MR. CARTMELL: Well, object to the form. Can I ask

Page 114

for clarification?
BY MS. GEIST:
Q. Right. So, Dr. Elliott --
MR. CARTMELL: Are you saying you want him to create an incidence rate nationwide from his own practice with a denominator?
BY MS. GEIST:
Q. I'm asking you, Dr. Elliott, you can't tell me what percentage of women that you are seeing represents women who have been implanted with the Avaulta product?
A. I see patients from all over the world, and so we have -- it's a unique practice that I have. I have yet to see, and I would like to see, Bard's numbers of exactly how many have been put in. That would be very helpful. But my practice is not going to reflect, you know, what that true incidence is. That just reflects what comes into my clinic.
Q. Right. So you don't know what the incidence rate is, whether it's high, whether it's low, whether it's someplace in between, for the complications relating to the Bard Avaulta products?
MR. CARTMELL: Object to the form.
BY MS. GEIST:
Q. You don't know what that incidence rate is, true?

Page 115

MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. I have papers on Avaulta, Avaulta Plus, describing their complication rate, and so that's all I can go off of. If they're talking 11, 20, 30 percent on short-term studies, if we extrapolate that, and those are in the hands of highly trained individuals, so if we just take those conservative numbers on short-term studies, then I can give an estimate. But, again, we need to provide the denominator.
Q. And we don't have that, correct?
A. Oh, it's available. Bard has not given it to us.
Q. Well, I'll just move to strike that. I don't know what that's based on.
How do you know that it's available?
A. You're telling me that a company in the United States that is designed to make money does not know how many products they sell and they're going to implant it? Then that sounds like a company that's not following their data very well. Cadillac knows how many cars move off their showroom.
Q. So you're making certain assumptions about what Bard knows; is that fair to say, Doctor? You don't have any basis for saying that?

Page 116

MR. CARTMELL: Object to the form.
BY MS. GEIST:
Q. Is that an assumption?
A. An assumption based upon experience, and I would -- I would really hope that Bard did the responsibility -- responsible thing and know how many products moved.
Q. Based on what experience? Have you ever worked for a medical device company?
A. I've been a consultant for some, yes.
Q. Have you ever worked as an employee for a medical device company?
A. Well, no. I've been a consultant for some in the past, so...
Q. Have you ever been a consultant for a manufacturer of a pelvic mesh product?
A. As a consultant, yeah. But we can just leave it on the table that it's acceptable for Bard not to know how many products have moved and have been implanted in women, if that's what you're telling me.
Q. No. That's not what I'm telling you, Doctor. I'm asking you what your basis is for your statement that you think Bard can just give you the denominator?
A. Bard knows how much money they made. Every company knows how much money they've made in the United

Page 117

States. They file tax returns. They know how much money is made. They would know. They'd be able to follow their subsections. There's a line, Avaulta, et cetera. And they're going to know what products make money.
Also, I read, in one of the depositions, that one of the individuals, when they're asked to file a 522 for the federal government, that he said it's not making enough money to go through the extra work, so they know.
Q. Do you -- do you understand, Doctor, there is a difference between products sold and products used or implanted?
A. Mm-hmm. Yes, I do.
Q. Do you know if Bard has the data you're talking about to even come up with the denominator?
A. If they --
Q. Do you know?
A. Absolutely, they do.
Q. What do you base that on?
A. Experience, because I'm also involved with the buying and selling of products at my institution. And if a company sells a product to an institution and the hospital buys a certain number of products and then five months later they have to sell more products back, that means the product moved.

(Elliott Deposition Exhibit No. 3 was marked for identification.)

BY MS. GEIST:

Q. Let me show you what I've marked as Exhibit 3 to your deposition, Dr. Elliott. And let me show it to counsel first because, for whatever reason -- I apologize -- I don't have another copy.

And, just for the record, Doctor, as Exhibit 3, I've handed you an article by Blandon and others published in the Journal of International Urogynecology in 2009. Do you see that?

A. Correct.

Q. And this was on your reliance list?

A. Correct.

Q. And, in this study, Doctor, this was actually a Mayo Clinic study, correct?

A. Correct.

Q. And who are Dr. Blandon, Gebhart, Trabuto, T-R-A-B-U- --

A. Trabuco.

Q. Oh, I'm sorry. That's a C. T-R-A-B-U-C-O, and --

A. Klingele.

Q. Yeah, thank you. K-L-I-N-G-E-L-E.

A. Blandon was a fellow, John Gebhart is the --

in charge of urogyn. He's the chair of urogyn. Manny Trabuco is a former Mayo fellow and urogyn and then staff, and the same thing with Chris Klingele.

Q. So one of the lead authors of the article was the chair of the urogynecology department at Mayo?

A. Correct.

Q. Is he still the chair of the department?

A. I think Klingele is now.

Q. And this paper is entitled, Complications From Vaginally Placed Mesh in Pelvic Reconstructive Surgery, correct?

A. Correct.

Q. And it refers to the experience these physicians had with women who were referred to the Mayo Clinic from all across the country, correct?

A. I can't speak to where they all came from.

Q. Referrals to the Mayo Clinic, I thought you just told me earlier, come from all over the country?

A. That is correct.

Q. Okay. And this paper looked at a number of different products that were used to correct pelvic organ prolapse, correct?

A. Correct.

Q. And what the authors did in this paper was to go back and take a look at women referred to the Mayo

Clinic from January 2003 through September 2007, correct?

A. Incorrect.

Q. I'm sorry?

A. Incorrect.

Q. How is that incorrect?

A. You said these women were referred to the Mayo Clinic. This is -- I mean, this is just into one department and a few of the staff. So it's not reflecting all of the patients that were sent in.

Q. Well, if you look at -- if you look at the article, it states, We retrospectively identified patients referred to our institution from January 2003 through September 2007 who had complications after vaginal placement of mesh. Did I read that correctly?

A. Correct.

Q. So it's saying the institution. It's not talking about a particular department, is it?

A. It is, because that's just reflecting their practice and that were referred into their department.

Q. So this is -- this is limited to the urogynecology division?

A. Pretty much, though I believe there is one patient of mine in there. But most -- this does not reflect my practice or the other female urologists in

our department.

Q. And over the four and a half -- approximate four-and-a-half time period, there were 21 patients, in that four and a half years, identified who had complications after vaginal placement of mesh?

A. Correct.

Q. Is that right?

A. That's what they report, yes.

Q. So more than four years and only about 21 patients, so maybe five per year, referred to the Mayo Clinic urogynecology department with mesh complications, correct?

A. Yeah. Somewhat, but that's somewhat very misleading.

Q. Well, is my math wrong?

MR. CARTMELL: Let him finish. Let him finish. Go ahead.

BY THE WITNESS:

A. This is 2003 to 2007. Avaulta wasn't even on the market. Most of the other ones weren't on the market. It's only Prolift. Prolift came out on the market in 2005. So this is dealing with the IVS tunnel and all of those type of things. And this is -- remember I mentioned there is delayed effect of the complications. So this is right when 2007, 2008, when

Page 122

we're starting to see this uptick, and that's what this is reflecting.

Q. So there is nothing inaccurate about what I just said, in terms of over a four-and-a-half-year period, there were 21 patients referred to Mayo for complications of mesh, approximately five per year during this time period?

MR. CARTMELL: Object to form.

BY THE WITNESS:

A. That is still incorrect. It's from 2003 to 2007. That does not reflect today's numbers.

Q. I didn't say it did. I'm talking about a four-and-a-half-year time period, acknowledging it's 2003 to 2007, there were approximately five patients per year referred to the urogynecology department at Mayo for mesh complications. Isn't that what this paper is looking at?

A. Well, I don't know. I would have to look over the paper again. Is this reflecting all of the patients they saw during that or just the ones that went to surgery? So that would require me to read the paper.

Q. Well, it's on your reliance list. Had you read it before?

A. Of course I've read it. I've read it multiple times, but I can't remember every word that I read. So

Page 123

in order to answer your question carefully -- and this is actually a very important point -- this may just reflect 21 that went to the OR.

Q. Well, Doctor, it actually doesn't. And if you look with me on the results section on the very first page, it provides a nice summary. And, it says, Complications included mesh erosions in 12 women, dyspareunia in 10, and recurrent prolapse in nine?

A. Okay. That still is not saying the denominator.

MR. CARTMELL: Do you want him to read the whole thing and let you know the answer?

BY THE WITNESS:

A. Because it's going to be in the paper. That's a very important issue. Because you just raised the issue about Bard not knowing the denominator and the numerator. This, I don't know if this is the denominator, all patients who came in during that time period or just the ones that went to the OR, because that's completely different. Because, remember, in my practice, only 25 percent of the patients I see end up going to the OR because I can't fix the other ones.

Q. Doctor, if you look at the results section --

A. That's not the results section. You're reading the abstract. Okay. That's the quick and

Page 124

dirty. In order to read a paper correctly, you have to read the entire paper.

Q. Okay. Well, I'm trying to be efficient and move us along. If you think that that section, the quick-and-dirty section of the article, says something different than what's in the text --

MR. CARTMELL: Just have him read it.

BY MS. GEIST:

Q. -- let me know.

A. I will read the paper because, again, you can't just quote one line and then extrapolate. That's why you need to know the whole thing. So if you want, I can review it.

MR. CARTMELL: Just go ahead and read it.

BY MS. GEIST:

Q. Well, let me ask you one question before you start reading it because I don't want to waste too much time. Under the Results section, it says, 16 patients were managed surgically.

A. Okay. Again, that's the abstract. That's not the results section. That's the abstract section. That's the results section of the abstract. That's different. Remember, I'm on 16 journals that I review, and I was best reviewer two years in a row for female urology. This is what I do for a living.

Page 125

Q. Yeah. I understand that. But how many times have you -- have you seen an abstract provide a summary like that specifically telling you 16 patients were managed surgically --

A. Yeah.

Q. -- and there's something different in the actual body of the paper?

A. No. That part, one line, 16 managed surgically, is correct. But you're only given, probably, 150, 200 words to do it. So, again, I don't know what the denominator is going to be.

And I'm more than happy to read the paper, and it's a very good paper. This is one of the first ones out there. But now there's been subsequent others, you know, Karram and Zimmerman and things like that, which have larger numbers than this. But this is one of the first ones to raise the awareness of this problem.

Q. So my question is, Doctor, the paper, if you go to the discussion section of the paper, the authors conclude that the incidence rate of the complications is unknown, correct?

A. I don't -- I don't know. I would have to see that line. It sounds like it would be -- you read accurately. I just want to know where you are, though.

Q. Sure. I'm on page 527 under Discussion?

Page 126

A. Okay.
Q. I'm not in the abstract. I'm in the body of the paper.
A. Okay.
Q. The authors of the paper conclude that the incidence of the complications are unknown, correct?
A. Yeah. Although -- let's see. I have to read the sentence before it. Okay. Yeah. As the use of synthetic materials in the pelvic reconstructive surgery increases, this is right when they came out and right when there is a big increase in numbers, so do the complications specific to their use. Although the incidence of these complications is unknown, our series demonstrates that, when they occur, multiple interventions may be required and bothersome and occasionally life-changing symptoms may persist.
Q. And, at this point in time, there were four trocar-based implant systems marketed in the U.S., including Bard's Avaulta product, correct, as noted in this paper on page 524?
MR. CARTMELL: Is that Sofradim's Avaulta? Is that the one that Bard -- because I don't think Bard's product was on the market at that time.
BY MS. GEIST:
Q. Doctor, will you look with me at the second

Page 127

page of the article on page 524?
A. I'm there.
Q. If you go down towards the middle of that paragraph --
A. Which column?
Q. I'm on the --
A. The first or second column?
Q. I'm on the left-hand side, second paragraph, beginning with the word Options?
A. Okay.
Q. Okay. Are you with me?
A. Yes, I am.
Q. All right. In the middle of the paper, in the middle of that paragraph, rather, it says, Four trocar systems are currently marketed in the U.S. Do you see that? Doctor, do you see that?
A. I'm looking.
Q. And it lists the Gynecare product?
A. I'm not there yet. Four -- okay. Four. Four trocar systems are currently marketed, correct.
Q. And there's the Prolift product from Gynecare, right?
A. Correct.
Q. The Apogee product from AMS?
A. Correct.

Page 128

Q. And the Avaulta product from Bard, correct?
A. Correct.
Q. And the authors of the paper did a retrospective study of all women referred to the urogynecology division from January 2003 to September 2007 who had complications after procedures using transvaginal mesh. That's what this paper looked like, correct -- looked at, correct?
A. That's what they state, yes.
Q. And the paper also notes that the authors of the paper didn't perform the actual implant procedures. The women were referred from outside institutions, correct?
A. Correct.
Q. And the authors' review of the database, this retrospective review, identified 22 women who were referred to the department during that time period with complications, correct?
A. Correct.
Q. And if you look at Table 2 of the study, are you there with me, Doctor?
A. Yes, I am.
Q. It lists the type of mesh products that the women who experienced complications had implanted. Do you see that?

Page 129

A. Yes, I do.
Q. And of the 21 women listed who were referred to the Mayo Clinic, there is not a single patient on this list who had the Bard Avaulta product implanted; is that right?
A. By the way they have it listed here, that is correct.
Q. If you go with me to page 530 of the article, Doctor --
A. Okay. I'm there.
Q. -- the authors note that the questions of what degree of training is sufficient and who should be performing these types of procedures remain highly debated. Do you see that?
A. Yes.
Q. And do you agree with that?
A. Yes.
Q. Would you agree, Doctor, that such a surgical technique and surgeon training and experience are critically important in a good outcome for any surgical procedure?
A. The -- within limits, the more expertise the data has shown that the results are better. That is correct.
Q. And what about with transvaginal mesh in

Page 130

particular? Would you agree with me that surgical technique and skill plays a very critical role in determining whether or not a woman may have complications?

A. I would somewhat disagree because there are some high-volume, world class surgeons, I can think of the French group and others for specifically with prolapse who have implanted, you know, 700, 800, and they still have an unacceptably high complication rate.

Q. Are you aware that there are very skilled and highly reputable pelvic floor reconstructive surgeons who still use transvaginal mesh today?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. I'm not familiar. As far as the transvaginal mesh or are you talking about the transvaginal kits?

Q. Transvaginal kits?

A. Transvaginal kits? Well, prolapse -- Prolift is off the market, Avaulta is off the market, Apogee/Perigee are off the market. I don't know about Boston Scientific. So if they are still putting them in, you know, I can't speak if they are. I have not heard of anybody.

Q. You're not aware of anyone still using these types of products?

Page 131

A. No.

Q. Would you agree with the conclusion by the authors from the Mayo Clinic and this study, Doctor, that there seems to be an inconsistency in the techniques by implanters?

A. Yeah. I can't speak to that. I think it's a valid point. Again, I can't speak to that with any accuracy.

Q. You don't have any opinion on that?

A. Well, no. I do have an opinion. If they're going to be following the IFU correctly and they're not told how high to dissect or how deep to go in the tissues, where to put the trocars, how much tension to put the trocars in, there is going to be some variability. So it seems to behoove the company to make sure it's very, very clear on an innovative product like this.

Q. At least based on this review from the doctors at the Mayo Clinic, at this point in time, the other products available on the market from Gynecare and other manufacturers were presenting with more complications, at least for women referred to Mayo?

A. Well, I mean, there is going to be a selection bias here. This is just the people that have come in with a retrospective view. I'd have to look back and see when Avaulta came onto the market. Because, remember, the Prolift was 2005 and a lot more of those got implanted. So I would have to see when Avaulta was released and started to put in. Because then you have to look at the study two, three, four years on down the road. That's when we start seeing the complications. Like Mickey Karram's paper and Philippe Zimmerman's paper, okay, those ones would be a little bit more reflective of complications.

Page 132

Q. At least, based on this paper, though, Doctor, there were no complications specific to the Avaulta product that was seen by Mayo at this point in time, correct?

A. Putting the qualifiers on there from January 2003, before it was even available, any of the mesh products were available, as far as the large ones, to 2007, you are correct. Of the 21 selected individuals who came in, there was not an Avaulta product on there.

Q. Well, and you keep saying available, Doctor. But if we go back and we look at the page, the second page of the article, the author specifically notes that the four trocar systems currently marketed included the Avaulta product; do you see that?

A. That is correct. They state that, but I don't know when that was available. Because, remember, they wrote this in 2009. So, again, you have to tell me when Avaulta was released and the first product was sold, and that would help me out tremendously.

Page 133

Q. I'm just sticking with what the authors found in this paper, Doctor.

MR. CARTMELL: Can I tell him the date it was released?

MS. GEIST: No. If you want to do your own examination, feel free --

MR. CARTMELL: Okay.

MS. GEIST: -- when I'm done.

MR. CARTMELL: All right.

BY MS. GEIST:

Q. Okay. Doctor, you can put that aside.

Let me -- let me move, Doctor, to your expert report and just start by asking you generally about pelvic organ prolapse. And you have a discussion, don't you, Doctor, generally of pelvic organ prolapse and some of the different treatment options for women experiencing that condition, approximately, page 5 to 12 of your report; is that right?

A. Correct. I wrote up a synopsis of 100 years of knowledge about pelvic organ prolapse, the etiology, et cetera, going through those pages you mentioned there.

Page 134

Q. And is it a fair summary that pelvic organ prolapse is a condition where the organs of the pelvic floor drop down from the usual supported positions into or through the areas of weakness in the pelvic floor?

A. For women, yes.

Q. And we are speaking about women, right?

A. Correct.

Q. Typically, the organs that we're talking about that prolapse are the bladder, the uterus, and the rectum?

A. And intestines.

Q. And intestines. And pelvic floor damage occurs, generally speaking, due to childbirth, correct?

A. Childbirth, age, obesity, chronic cough. There are multiple factors that all play a role, but childbirth would probably be the number one.

Q. Physical labor or chronic issues with straining or constipation as well could be risk factors for prolapse, true?

A. Correct. Anything that would be under the criteria of Valsalva effort, which just means straining.

Q. And that results in a deficiency in the support of the organs that we just finished talking about, right?

A. It means that the musculature, the tendon

Page 135

support, so to speak, are weakened with childbirth, and then with time, age, et cetera, all of the factors we mentioned, the structures slowly descend.

Q. Okay. And that's because, as I said, there is sort of a deficiency in the support for those organs; is that a fair summary?

A. I wouldn't say -- well, the fact that there is a problem reflects that there is a deficiency, if you want to call it that. But I wouldn't call it that. It's that there is a weakness or a tearing. With childbirth, there is an extreme amount of tearing. That's why it hurts. Okay. If childbirth didn't hurt, there wouldn't be the tearing of the muscles. So the muscles are also a big part of the support of this, too.

Q. Okay. So there's -- the muscles are not as strong, if you will, as before a woman had experienced childbirth?

A. There's -- and, again, it's damage of the whole pelvic structure, the support. So we can't think of it in just muscles, just tendons, just collagen, et cetera. It's the whole unit has been damaged.

Q. And do you treat women in your practice who experience pelvic organ prolapse?

A. Daily.

Q. And has that always been part of your

Page 136

practice?

A. Yes. Since 2000, yes.

Q. And what percentage of your practice is devoted to clinical experience in treating women versus teaching?

A. Well, I'm -- I always have a resident with me. So I'm 100 percent teacher, but I am 100 percent clinical. So every other day I'm in the clinic and the next day I'm in the operating room.

Q. And, based on your own experience, I assume that you would agree with me that pelvic organ prolapse can negatively affect a woman's life?

A. The quality of life can at times be impaired with this, but it's important to stress that it is a quality of life issue.

Q. It's not a life-threatening condition, correct?

A. In the United States, that is exceedingly rare for it to be life-threatening. I've only seen that one time.

Q. But it can impact a woman in many different ways in terms of symptomatology?

A. Correct.

Q. It's a very prevalent condition in the United States, somewhere between 30 to 50 percent of all women

Page 137

are affected by some degree of prolapse; is that a fair summary?

A. Well, that's going to be difficult to say because there are -- it depends on how the study is run, if it's anatomic prolapse versus subjective symptomatic prolapse again.

So I don't know if we need to stop for out there.

MR. CARTMELL: We don't. Go ahead.

BY THE WITNESS:

A. So I almost have to start over with that, because that's very, very important, because just the fact that there is an anatomic prolapse does not mean there is a problem. You have to look at the subject of everything. So I would be hesitant to say the number is up to 30 to 50 percent. That would be pretty on the high side. But, to answer your question, it is a prevalent problem.

Q. Would you agree with me that, at least what the literature tells us, is that maybe 300,000 women undergo surgery a year for the repair of pelvic organ prolapse?

A. Yeah. I have not heard. I have no reason to doubt the accuracy of that. I have not heard a specific number. It's a large number.

Page 138

Q. Well, what are some of the signs and symptoms that a woman may experience if she has pelvic organ prolapse?

A. We have to break it down into -- well, there is a lot of different types of symptoms and things: fullness; something falling out; pressure, potentially; pain very, very rarely. Pain is usually the exact opposite. The higher the prevalence of pain, the lower the incidence of pelvic organ prolapse. So pain is not one of them usually.

Q. Pain usually indicates something other?

A. Something else, correct. I said fullness. Can we stop? Because whatever is going on out there is distracting me a whole bunch, the noise.

MS. GEIST: Yeah. Let's go off the record for a minute.

VIDEO TECHNICIAN: We are off the record. The time is 12:20 p.m.

(Whereupon, at 12:20 p.m., a recess was had for lunch.)

Page 139

A F T E R N O O N S E S S I O N

VIDEO TECHNICIAN: We're back on the record. The time is 12:58 p.m.

WHEREUPON:

DANIEL S. ELLIOT, M.D.,

called as a witness herein, having been previously duly sworn, was examined and testified as follows:

DIRECT EXAMINATION (Continued)

BY MS. GEIST:

Q. Dr. Elliott, before we took a break, we were talking about the signs and symptoms that a woman might experience when she's having pelvic organ prolapse. Do you remember that?

A. Yes, I do.

Q. And you started telling me about some of the signs and symptoms and said that pain is probably indicative of some other medical problem or condition, correct?

A. Pain -- pain is usually not consistent with pelvic organ prolapse.

Q. And we talked about the feeling of like something falling out?

A. Fullness, pressure, falling-out sensation.

Q. Falling-out sensation, we're specifically talking about a woman's vagina, correct? She feels like something is actually falling out of her body?

A. Correct. With standing, lifting, as the day goes on, that's the most common thing I hear is, again, something is falling out.

Q. In some women who have a more severe type of prolapse, you can actually visibly see something extruding beyond the entrance of the vagina, correct?

A. Correct. In severe cases, it can actually look like a baby's head crowning.

Q. And then some women have also -- I'm sure you've heard in your own experience and practice -- talk about a feeling of heaviness as well?

A. Yeah. That's the fullness, pressure.

Q. And some women, I'm sure you have known from your practice, also have issues with being able to urinate or void or defecate as well because of pelvic organ prolapse?

A. Not necessarily. Urination symptoms, like not being able to urinate, has been reported. That's rare. Frequency, urgency, usually the bladder actually works fairly well. Defecation, usually they're going to have a problem -- the constipation is going to cause the prolapse, not the prolapse cause the constipation.

Q. And some women, Doctor, I'm sure you've seen in your practice, have issues with sexual intimacy, being able to experience sexual intercourse or wanting to experience sexual intercourse with their partners, true?

A. Correct. There could be physical barriers and also psychological barriers with the prolapse, embarrassment and things like that.

Q. And often, Doctor, but not always, there's some sort of incontinence associated with pelvic organ prolapse; is that also true?

A. There can be incontinence present before surgery and also if it's not corrected after surgery. It's called occult incontinence.

Q. And when a woman presents with these symptoms and signs of pelvic organ prolapse, what are her options to resolve the problem?

A. It depends upon the severity of the condition, the health of the patient. There's multiple different factors.

Q. So there is nonsurgical options, correct?

A. Correct. Nonsurgical, and there's observation, nonsurgical and then surgical.

Q. So the observation is sort of the wait-and-see approach, live with it, and see if you can deal with it in your daily life on a daily basis?

A. If it's minimally symptomatic, there's nothing

Page 142

wrong with observation.
Q. And some women choose that, correct?
A. A large number do, yes.
Q. After consultation and discussion with their physician?
A. Yes. It should always be offered to the patient, yes.
Q. And it's her decision ultimately?
A. I can only speak to my personal practice, but I always leave it up to the woman to decide.
Q. And then a nonsurgical option would be the use of a pessary; is that correct?
A. Pessaries, pelvic floor strengthening exercises, vaginal estrogen replacement, the conservative options.
Q. And what are sort of the -- pardon me. Strike that.
What are some of the problems or potential side effects if a woman chooses to use a pessary?
A. A pessary can have -- first of all, probably the most common thing is the pessary can fall out. There has to be maintenance for it. It has to be changed. It has to be cleaned, doctor visits, those types of things. If it's not taken care of appropriately, there could be vaginal erosion,

Page 143

discomfort.
Q. Pain as well?
A. Pain, yeah.
Q. For some women?
A. No, that definitely can happen.
Q. And in terms of surgical options, Doctor, the goal of any surgical repair of pelvic organ prolapse is to provide some sort of support for the organs that have less support than they used to have?
A. No. The goal of surgery is symptom relief.
Q. The goal of pelvic organ prolapse is not to lift up or put the organs back to where they were originally?
A. I think, if you look at studies out there, what the patient wants is they want relief of their symptoms that may be achieved either through counseling and reassurance or through surgery. Then when you do surgery, that will usually mean elevating the organs back up to a normal or closer to normal position, but it does not have to be anatomically perfect repair.
Q. But, in order to relieve the symptoms and problems that a woman experiences, which is why she goes to see a doctor, you are trying to correct the anatomic defect; is that true?
A. My goal is to relieve the symptoms. I may do

Page 144

that through an anatomic repairing the prolapse and getting back to a normal anatomic position. But if I achieve just anatomic success, that does not necessarily correlate to subjective is the patient happy or not.
Q. Is anatomic success important or not in terms of the goal of the pelvic organ prolapse surgery, repair surgery?
A. For me, not to belabor the issue, but the goal is subjective relief. If I do a surgery and I take a woman with a Grade 4 prolapse and six months later she comes back and she has a Grade 2 prolapse, but she's thrilled with the results, she's relieved, that's a success.
Q. So you're looking at both improvement in the anatomic structure as well as improvement in the symptomatology?
A. I do it the other way around. Improvement of symptomatology, is the patient happy; and then, secondly, if the -- if there is an anatomic repair that is pleasing, the anatomic repair is pleasing to the surgeon, not necessarily to the patient.
Q. Would you agree with me that both are goals of a pelvic organ prolapse procedure, a surgical procedure?
A. This is a quality-of-life problem. So the goal is to improve the quality of life. If I've

Page 145

improved the anatomy but the patient is not happy, that's not successful surgery.
Q. Well, the way to improve the quality of life, as you've just indicated, is to address and improve the symptoms, correct?
A. Correct.
Q. And in order to do that, you need to be addressing the anatomic defect or problem, true?
A. Correct.
Q. That's what you're doing in a surgery, correct?
A. We are -- we are improving the support for the organs.
Q. And there is different methods to go about improving the support of the organs, correct?
A. Correct.
Q. There's a number of different options?
A. There are quite a few options, yes.
Q. So let's talk about some of those options briefly. Native tissue repair is one of the options?
A. Correct.
Q. And have you done that in your own practice?
A. That's the majority of what I do.
Q. And has that always been the majority of what you've done in response to a woman who decides to have

Page 146

surgery to repair organ prolapse?
A. Correct.
Q. The majority of the prolapse cases that you've seen, Doctor, I assume relate to bladder prolapse or a cystocele?
A. No. There's going to be a mix. There's going to be -- we won't necessarily call it cystocele. It would be an anterior, apical, or posterior prolapse. The only prolapse I do not do is when there is a concurrent uterine prolapse. My GYN colleagues take care of those.
Q. It seems, based on my review of the literature, Doctor, that the anterior prolapse is the more prevalent or more frequently seen type of prolapse; is that right?
A. That's probably fair. It's probably a little bit more symptomatic.
Q. It's the reason why more women go to the doctor for any other type of prolapse, true?
A. I would say that that's fair. The anterior compartment is the more problematic one.
Q. It seems to be more susceptible to prolapse for whatever reason?
A. Correct.
Q. And what are some of the potential adverse

Page 147

events or risks or side effects if a woman chooses to have a native tissue repair for an anterior defect?
A. An anterior repair, she could have postoperative bleeding is a possibility, development of urinary incontinence, recurrence of her prolapse is probably the most common ones.
Q. So she could actually develop de novo incontinence after an anterior repair done natively?
A. Not necessarily de novo. It's what's called occult incontinence, O-C-C-U-L-T. It means the incontinence was there prior to surgery. But because the bladder was falling down, it's not manifested. And then when you put the bladder up into a more anatomic position, incontinence is discovered. So it's not like we're causing it. We just uncover it.
Q. Or sort of exacerbating it using the native tissue repair?
A. No. We're just uncovering it. It was there. Because when the urethra is down like this, the woman doesn't leak. When we put it back up like this, the woman can leak. So it was there. That's what you're testing before surgery to make sure that does not happen after surgery.
Q. So are there circumstances where there is de novo incontinence after an anterior repair done

Page 148

natively?
A. It can happen, but that's why almost always I'm doing a concurrent sling at the same time of the anterior prolapse.
Q. But it can happen, true?
A. It can happen, yes.
Q. In terms of other potential adverse events or complications from native tissue repair, I assume you would agree with me that there is also a risk of infection with any type of surgery we've been talking about?
A. Vaginal infection you're referring to? Because I've never seen that with my patients.
Q. Is that sort of well-established in the literature that there is a risk of infection with any surgery?
A. Well, with any surgery, that's a possibility. Transvaginal surgery is a unique surgery with the vagina usually being fairly vascular. So an infection of the vaginal tissue is exceedingly rare. It could possibly happen. In my 15 years at a tertiary center, I've never had one patient develop a vaginal infection after one of my repairs.
Q. But you're not disagreeing with me that infection is a potential adverse event of a pelvic -- of

Page 149

a native tissue repair just like any other surgery?
A. I'm saying that I'm not disagreeing with you, but I'm saying it can happen very, very rarely.
Q. Okay.
A. And I've never seen it.
Q. And how about complications such as pelvic pain and dyspareunia? Can those also develop after a woman undergoes a native tissue repair?
A. It's a possibility. I mean, in my experience in my personal practice, 15 years at a tertiary care center, I've had one patient, because we watch our patients very closely, with de novo dyspareunia afterwards, and we were able to then go after surgery and trim a suture and that resolved her dyspareunia.
Q. But you're not disagreeing with me, Doctor, that pelvic pain and dyspareunia are known potential complications from a native tissue repair to improve pelvic organ prolapse?
A. In the very rare circumstance and mild, it could possibly occur with those caveats.
Q. Would you agree with me, Doctor, that, if a woman has diabetes or is a long-term smoker or has chronic obstructive pulmonary disease, among other comorbidities, she may be facing greater challenges with healing after a native tissue repair?

Page 150

A. Well, you mentioned multiple different factors there. So we have to go one by one.

Q. Okay. Let's go one by one.

A. Diabetes, I don't know of anything in the literature relative to transvaginal surgery of increased risks or complications. I've never seen that, never heard it reported, never in any meetings or discussion with colleagues. COPD, COPD has an increased risk for recurrence of the prolapse, but not infections. Smoking, for native repairs, I've never seen one document saying that increases the risk for infection.

Q. Do diabetics or smokers generally have more challenges or issues relating to healing after any type of surgery?

A. Well, when you include any type of surgery, that's a different story. If you're talking transabdominal surgery with a major -- a morbidly obese patient who smokes, that's different than transvaginal surgery because then you have an extensive fat, adipose tissue, that does not heal well and then, by all means, they are at increased risk for infection. But transvaginal surgery, we don't have to deal with the fat and the poor healing.

Q. So you don't agree with me that somebody who is a smoker, for example, or somebody who is a diabetic

Page 151

would have more challenges or problems healing after a vaginal surgery?

A. I think that there is going to be limited data as far as a significant impact upon healing with native transvaginal repair with smoking, and I forget what the other one you said. It was COPD was -- COPD would be a nonfactor in that. COPD would be caused by the smoking. COPD has an increased risk for recurrence of prolapse. Oh, you said diabetes. I can't think, off the top of my head of a paper that shows an increased risk for vaginal infection.

Q. Well, how about just a general healing? I'm trying to see if you agree with me that, as a general statement, smokers or diabetics have more challenges and problems healing after, for example, a native tissue repair?

A. I'd disagree with that. I have no experience of ever seeing that, and 40 percent of my patients are obese with diabetes. And so I have not seen that with vaginal. But, again, if you open -- if you do an abdominal incision, that's a different story. Then I will agree with you, but not for transvaginal work.

Q. In addition to native tissue repair, there is also the abdominal sacrocolpopexy, correct?

A. That is another one of the options from an abdominal route, yes.

Page 152

Q. And have you used that option yourself in your practice?

A. Yes. That's what I was originally trained to do starting in 1999.

Q. And that procedure involves the placement of a biologic or synthetic mesh via the abdominal route, correct?

A. Correct. Though most of the time they're not using biologics anymore. They were shown not to work well.

Q. So, in this particular discussion, biologics don't work as well as synthetic or polypropylene mesh; is that right?

A. Well, no. I say that biologics do not work as well. There is a very nice paper from a Dr. Brubaker from 1999 or 2000 talking about using cadaveric tissue or biologics for sacrocolpopexy, and the failure rate was quite high. It wasn't strong enough to hold things up.

Q. Right. They're not as strong as synthetic or polypropylene mesh, true?

A. No. That is correct.

Q. And that's borne out in the literature?

A. That's a fair statement.

Page 153

Q. And then you need strength because you're trying to augment the lack of strength or the weakness in the ligature in the pelvic floor, correct?

A. I would disagree. It needs strength because, when you do this procedure, you're holding the vagina up and sewing it to the sacrum. So you need to have strength to be able to hold that up. That's a completely different dynamic than the transvaginal work, which is working on suturing in different locations. This is holding up almost literally straight up to the sacrum.

Q. Do you continue to place polypropylene mesh through the ASC procedure in your patients?

A. The abdominal sacrocolpopexy route I still do. I have one on Monday, but it is the minority of my patients. Now, the majority are being done robotically. It's the same -- it's the same procedure, just with a different way of gaining access to the vagina and the sacrum.

Q. And you also do that procedure laparoscopically, correct?

A. Not anymore. It's -- originally the first one, when we started doing, it was laparoscopic-assisted. That was just a technical aspect. It's pure robotic now.

Page 154

Q. You moved on from the traditional ASC -- ASC repair -- and I'm shortcutting just so I don't have to say it 5,000 times. You moved on from the traditional ASC repair to the laparoscopic approach to the robotic approach; is that a fair statement?

A. No. When I was trained in 1999, I trained with a GYN department at Baylor College of Medicine in Houston. At that point in time, the standard of care was to do this abdominally. And, as I was fellow, I felt that this would be very amenable to doing this robotically. Other people had tried it laparoscopically, but it was very technically difficult, challenging work. But the robot bypasses that.

So when I got back on staff in 2002, I approached my colleague who does robotics. So he's fellowship trained in robotics. And together we did the first one. The laparoscopic-assisted laparoscopy was only to gain access. It was kind of a -- it's essentially a nonentity in this procedure. It's pure -- it's robotic.

So I never had that laparoscopic middle point like you mentioned. And so now the overwhelming majority of them I do is robotic sacrocolpopexy unless there is factor that we can't do it robotically.

Q. Okay. Understood. And would you agree with

Page 155

me, Doctor, that, at one point in time for surgeons practicing in the area of pelvic reconstructive -- female pelvic reconstructive surgery, most surgeons moved on from a native tissue approach to the ASC approach, the abdominal approach?

A. I think there's going to be two big schools of treatment for prolapse, and it depends upon -- probably upon where you trained and the expertise of the people you trained under. Where I trained they felt that certain of the transvaginal repairs, sacro- -- sacrospinous fixation maneuvers were dangerous and they wanted to do a transabdominal. Other GYNs will say the opposite. So I just happened to come up with one who did it transabdominally.

Q. There is a number -- just by way of summary, there's a number of different surgical approaches to treating pelvic organ prolapse. Would you agree with that?

A. There are quite a few, yes.

Q. Different doctors use different approaches depending on their own experience, their own skill, and their preference, true?

A. That is a fair statement.

Q. And the transvaginal mesh was also developed as one of these options for doctors to use?

Page 156

A. That's true.

Q. Like the ASC procedure, that was developed because of some of the problems that doctors were seeing with native tissue repair in terms of recurrence rates?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. I partially agree with that. You are correct, but some of it was the perceived problems of native repairs. But it was addressed to try and reduce the risk of recurrence.

Q. All right. So let me make sure I understand. You agree with me that originally most doctors used the native tissue repair, and that goes back some time?

A. The native tissue repairs have been around since surgeons have tried to fix vaginal prolapse.

Q. And then, at some point in the mid-1990s, the ASC procedure became what I will refer to as the gold standard in repairing pelvic organ prolapse through surgery?

A. I wouldn't be able to tell you. I mean, gold standards are relative. If you talk to somebody else, it won't be a gold standard. But in the 1990s, I don't know. There's work by Timmons and Addison at Duke going back to the '50s and '60s looking at sacrocolpopexies. So I think it is very fair to say that ASC is considered

Page 157

the highest anatomic success rate procedure. When that happened, I can't give you a date on that.

Q. And then would you agree with me that doctors wanted to try and explore other options that were less invasive and had better outcomes than the ASC?

A. I think it's fair to say that the ASC is a -- it's a large surgery. There's a large incision made. There's a fair bit of recovery. The trans- -- and then, when people try transvaginal, there was a perceived -- perceived higher failure rate with it. So some of the transvaginal mesh kits were designed to introduce that to hopefully reduce the morbidity or avoid the morbidity of the ASC.

Q. And you understand that, that was the reason and the purpose behind the development of that type of technology in order to reduce the morbidities and issues seen with the ASC approach?

A. Correct. And that's a laudable goal to be searching for a different way of doing it.

Q. It's a good thing for medical device companies to explore other options for surgeons to use to treat their patients with pelvic organ prolapse?

A. Yeah. I encourage innovation, safe innovation.

Q. With -- we talked about some of the risks and

Page 158

side effects associated with native tissue. Is there also the potential side effect that a native tissue repair could create or cause a shortening and a narrowing of the vagina?

A. If you're doing just an isolated compartment, an anterior repair or posterior repair, that's unlikely. If you're doing an anterior and a posterior repair, that could happen. There could be some forced shortening of the vagina. Other procedures, like a sacrospinous fixation which is done transvaginally, the vagina would not be shortened. And then -- I can't recall if you asked this -- ASC does not shorten the vagina either.

Q. The ASC procedure, while it may have been more successful in terms of anatomic success compared to the native tissue, it was associated with more significant complications because of the abdominal approach?

A. Yeah. It's a bigger surgery, abdominal incision. So you could have abdominal wall infections and problems with that, bowel problems. It's rare. In our series of, now, almost exactly 100, we haven't had a single one of those types of problems. But, yes, that could happen.

Q. And there is a risk of mesh erosion associated with the ASC procedure?

A. That has been reported in our series. And, as

Page 159

I mentioned, 100 patients, which we're writing up the series on right now, we had, I believe, three in our first ten patients and then none after that with follow-up up to 12 years, 13 years now.

Q. So if a woman chooses the ASC procedure in consultation with her doctor versus the transvaginal mesh procedure, she could still experience an erosion of mesh, true?

A. As I mentioned, in our experience, it is highly unlikely, but something like that could happen.

Q. Similarly, there is a risk of pelvic pain and dyspareunia and infection associated with the ASC procedure as well, true?

A. It depends where you define it as far as infection goes.

Q. Well, let's stick with pelvic pain and dyspareunia.

A. Okay.

Q. The woman has the ASC procedure to treat her pelvic organ prolapse. There's also a risk of pelvic pain and dyspareunia associated with that procedure, correct?

A. I assume something could be possible; but in our series of now exactly 100, or almost 100 patients, with follow-up as of right now, we have not seen that

Page 160

one time.

Q. Have you seen that in the literature, though, setting aside your own personal experience?

A. Yes. There is an extensive amount of literature out there on the ASC procedure, and vaginal pain or dyspareunia has been reported in a minority of patients.

Q. And then, Doctor, I think, you know, in terms of sort of a chronology, we saw sort of a movement towards the laparoscopic sacrocolpopexy?

A. Well, the laparoscopic sacrocolpopexy is a relatively minor, minorly (sic) performed procedure because it is quite complicated. The robotic now is doing the lion's share of those procedures.

Q. Are there complications, adverse events, risks associated with either the laparoscopic sacrocolpopexy and the robotic sacrocolpopexy?

A. Yeah. There are risks with those procedures.

Q. What are some of the risks, potential risks and side effects associated with those procedures?

A. We warn individuals about the potential for skin infections, injury to the bladder during implantation, the potential for bleeding during the procedure itself.

Q. And you're using mesh in these procedures, as

Page 161

well, right, Doctor?

A. We are using a Y-shaped polypropylene mesh.

Q. So it's polypropylene mesh as you've just said, right?

A. Correct.

Q. And you're still doing that today. I think you told me you put one in last week, correct?

A. A couple weeks ago.

Q. I apologize if I asked you this, Doctor. Even though you're using the Y-shaped polypropylene mesh, as you've just told me, for these procedures, is there still a risk of mesh erosion associated with the procedure?

A. In our hands, in the last 90, the answer would be, no. In the first ten, yes. But that was a technical issue. We were dissecting too thin.

Q. So --

A. And then because -- I'm sorry to interrupt you.

Q. No. That's all right.

A. And because the mesh is a Y-shape, it does not have arms and we're able to lay it flat and it is through sterile ports, I believe that's why we're not seeing those problems.

Q. So in your first ten patients where you

Page 162

implanted Y-shaped polypropylene mesh using -- were these all the robotic approach or the laparoscopic?

A. Robotic.

Q. Robotic?

A. Yeah, but it's there are a few in there that were robotic-assisted. But, again, robotic-assisted laparoscopic, but the laparoscopic, again, was just to gain access. So it's really -- the easiest way to think about it is just pure robotic.

Q. Okay. So using the robotic approach to implant Y-shaped polypropylene mesh, the first ten patients experienced mesh erosion?

A. No. No. Three out of those ten did.

Q. Okay.

A. And that was because --

Q. So three -- I'm sorry. Go ahead.

A. That was a surgical -- it was technical issue. We were dissecting too thin on the vagina. Because as I mentioned, we were the first in the world to do it, so we had to somewhat figure it out. But then, since then, zero, and that's with, again, with nearly 13 years of follow-up.

Q. So just so I'm clear, out of the first ten patients, three out of the first ten experienced mesh erosion?

Page 163

A. Correct.

Q. I assume you obtain informed consents from your patients when you performed these procedures?

A. Correct.

Q. Do you include mesh erosion as a potential side effect or adverse event or complication associated with the procedure?

A. Yes. We discuss it with them. I tell them exactly what I just told you now. Because we look at our data very, very closely and follow these patients long-term, that, in the first ten, we had three and, since then, zero.

Q. Notwithstanding your improvement in erosion incidents since you first started, you still include it as a potential side effect or complication when you inform your patients, true?

A. We discuss it with the caveat of giving actually specific numbers and the risks.

Q. So you still tell them about it?

A. I tell them they have, in our series, you know, roughly, a 3 percent chance of it; however, if we look at the last 90, 0 percent chance.

Q. You're not excluding the possibility that any one of your patients who undergo this particular procedure could experience mesh erosion; is that fair to

Page 164

say?

A. Again, I've answered it. I tell them exactly what I tell you now. The first ten, three patients did it. We altered how we did it, 90 patients, and zero.

Q. So the answer to my question is, yes, you don't exclude the possibility that it could happen?

MR. CARTMELL: Objection. Asked and answered three times.

MS. GEIST: I don't think so.

BY THE WITNESS:

A. I'm very, very clear how I word it to the patient. I say it just that way. The first ten we had it in three and then after that zero.

Q. So, in your practice today, you don't exclude the possibility that it may happen to another patient, true?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Statistically speaking, if we were looking at it that way there's, in our hands, in the last 90, 0 percent chance of having it, and that's what I tell the patient.

Q. Well, then why do you include it on your informed consent? If there is zero chance that it's

Page 165

going to happen, why do you tell your patients about it at all? That doesn't make any sense, does it?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Sure. I think it makes perfect sense. I believe in full disclosure to the patient. The patient needs to know everything and they also need to know the potential risk with percentages.

Q. So, in other words, if it is -- if it is a true potential risk, not something hypothetical or something that could never occur, if it's a true potential risk, you tell them about it?

A. Well, I also give them statistics.

Q. I understand.

A. So I don't -- I don't just say carte blanche there is a risk. I say what are her -- their odds. Patients aren't -- patients want to know what are their chances of complication.

Q. You're not going to tell one of your patients, Doctor, about the risk of erosion if there is no chance it could ever happen? You wouldn't tell them about it if there was no chance?

A. I tell them, in the last 90, zero. So the odds of her experiencing it in our hands, if they're involved in that last 90, is going to be zero.

Page 166

Q. So, just so I understand, you -- sitting here today, you think there is zero chance of one of your patients experiencing mesh erosion from your current procedure?
MR. CARTMELL: Object.
BY MS. GEIST:
Q. Zero, zero chance; is that right?
MR. CARTMELL: Object. Misstates his testimony.
MS. GEIST: No. I want to understand his testimony.
BY THE WITNESS:
A. No. I am very, very clear with the patients and fully open with all of the pros and cons, because, again, we follow these patients very carefully, so I know what happens with them so they don't wander off and have a complication elsewhere. So we're saying, in our hands, first ten, yes. The first ten, if you look at it, 30 percent. The second group of 90 patients, 0 percent. And I say in our hands, when we do this, 0 percent chance.
Q. So you tell your patients about risks where there is a 0 percent chance?
A. I believe in full disclosure about everything good and bad that's happened in the past and the future. That was during the part of an early learning curve,

Page 167

too.
Q. Do you tell your patients about other risks associated with the procedure when there is 0 percent chance of those risks occurring?
A. I don't talk about dyspareunia because we've never seen it. In fact, in our series, we're seeing improvement of sexual functions.
Q. So you don't -- you don't -- so dyspareunia is not included in the informed consent for your current procedure, correct?
A. Because we have not seen it.
Q. Right. And erosion is included because you have experienced it in your own patients?
A. Not erosion, no. That's the wrong word.
Q. Exposure, extrusion?
A. Extrusion.
Q. I think we're talking about the same thing, are we not?
A. Well, no. But erosion -- erosion is into other organs. So I don't talk about that because we've never seen it, never experienced it.
Q. All right. So that was my bad terminology.
A. I talk about exposure.
THE REPORTER: I'm sorry.

Page 168

BY MS. GEIST:
Q. Hold on. Dr. Elliott, the court reporter is going to get mad at us. You talk about exposure or extrusion, right?
A. I mention it with the caveats that I've mentioned several times now.
Q. Okay. I assume you would agree with me, Dr. Elliott, that, in terms of options that a pelvic floor reconstructive surgeon has in his or her arsenal of things to offer to a patient, that there is no clear consensus among the medical community that one option is better than anything else for any given patient?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. You're referring to, I assume, transvaginal prolapse rate, specifically that? No, I would say that the consensus out there is that the sacrocolpopexy has the highest chance of a high quality permanent success. I don't think there's too many around there who are arguing about that.
Q. When you say the sacrocolpopexy, are you talking about via the abdominal approach or the robotic-assisted procedure?
A. Both, just the abdominal route.

Page 169

Q. Do you -- you've published pretty extensively, as we've talked about earlier, right, Doctor?
A. I've published quite a bit.
Q. Yeah. And a lot of your publications relate to the robotic sacrocolpopexy as we went through earlier, right?
A. Robotic and just abdominal, yes.
Q. And you published on that procedure specifically how it compares with other prolapse repair techniques, true?
A. Correct.
Q. And, in your publications, you've noted that options for surgical treatment include a number of things, such as the ASC, the laparoscopic sacrocolpopexy or the robotic sacrocolpopexy, right?
A. That sounds consistent with something I might say.
Q. Okay. And you've concluded, in your own publications, that it's still not clear in the medical community which of these approaches is the best?
A. I'd have to see that article and when we wrote that. You can just tell me the date.
Q. Do you want to look it up, or do you want me to give you a copy?
A. Well, if you have the copy right there, you

can just say the date.
Q. I don't have a copy. It's 2013, so just last year?
A. Okay. So 2013, that reflects the thinking going on in, roughly, 2010 when we started doing research on that. And then we're probably considering or thinking about the robotics. But, again, the robotics, originally, no one was doing them, and then it slowly got hold and now, in certain regions in the United States, it is the most common type of abdominal approach. Again, I have to look at what we were thinking at the time and relative to what.
Q. Well, this was -- this was just last year, right? It wasn't that long ago?
A. No. But that's when the paper comes out.
Q. Right.
A. But we start writing that paper two years, at least, prior. We then submit it. It goes through multiple revisions, and then it gets accepted and then six months or so later it gets published. Now, you should have on there when it was submitted and when it was published. So from the time a project is started until it comes out in print is usually about two years or so.
Q. Okay. Well, let me just mark this. I think

we're up to Exhibit 4, so I can ask you some questions about it.
(Elliott Deposition Exhibit No. 4 was marked for identification.)
MS. GEIST: Okay. I actually do have a copy this time. Doctor, here is yours. Counsel.
MR. CARTMELL: Thanks.
BY MS. GEIST:
Q. Doctor, just for the record, I've handed you what we've marked as Exhibit 4. And this is a copy of your article published in --
A. Yeah. This was in a requested opinion piece from Howard Goldman.
Q. And who is Howard Goldman?
A. He is a surgeon at -- in Cleveland.
Q. At the Cleveland Clinic?
A. Well, he's got a dual appointment there. I don't know how exactly it works. He's mainly -- I'm blanking on the place there in Cleveland. If Ben were here, he would know. I can't recall. Case Western?
Q. He's a --
A. No. That's in Chicago; isn't it?
MR. CARTMELL: No. Case Western is in Cleveland.
BY THE WITNESS:

A. I know Howard very well.
Q. Okay.
A. We can say, it's fair to say, he has a dual appointment of some kind in Cleveland, but he's mainly at the other institution that's there.
Q. He's pretty reputable in the area of pelvic floor repair?
A. He -- he is a very, very good, thoughtful person. He is a -- tends to be a pro-mesh surgeon and transvaginal kits, but he is a good person.
Q. Is he a good surgeon?
A. I've never seen him operate. Unless I've seen somebody operate, I can't attest to that.
Q. And you're aware that he still uses transvaginal mesh to repair pelvic organ prolapse?
A. I haven't spoken to him for a year, so I don't know what he's using now.
Q. At least, as of a year ago, were you aware that he was still using transvaginal mesh to repair pelvic organ prolapse in certain of his patients?
A. I can't say that. I didn't ask him that specifically. I don't know if he does. I know in the past -- all I can say to have accuracy is, in the past, he did use mesh kits. I cannot say what he's done now.
Q. If Dr. Goldman or any other pelvic floor

reconstructive surgeon is using transvaginal mesh in some of their patients for a treatment of pelvic organ prolapse, are they acting within the standard of care?
A. We would have to look at all of the parameters involved in that patient to be able to ask or answer that correctly. I do know of some in the past, of high-volume surgeons, that use mesh. And when we were at meetings, we would discuss it and I would be against their opinion, and they would be, obviously, for theirs. And if they put clarify -- clarifiers on there, on highly select, fully informed patients, perhaps, multiple revision patients who have failed everything else and are having a significant amount of problems and the patient knows all of the potential complications, there possibly would be a role for mesh in those types, but without mesh arms. So there's -- there's a lot of qualifiers on there.
Q. There are a lot of qualifiers on there.
A. And that's why we talk, because this is complicated, and this is what we talk about at meetings, at the highest level of meetings. You don't get any higher than the International Incontinence Society and the SUFU in the United States, and this is what we talk about.
Q. So, just so I understand, it's your opinion,

Page 174

Doctor, that there still -- still may be a role for the use of transvaginal mesh to repair pelvic organ prolapse depending on a number of particular patient factors --

MR. CARTMELL: Wait. Let her finish.

BY MS. GEIST:

Q. I don't know if I'm finished yet. Hold on. Let's strike that question and let me start again.

Would you agree with me, Doctor, there are still today, notwithstanding the controversy and discussion among the medical community, there still may be a role for the use of transvaginal polypropylene mesh to repair pelvic organ prolapse in certain patients?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Okay. I don't feel comfortable answering that question just as it is because I want those qualifiers on there, and it has to be, again, a high-volume, highly trained surgeon who is fully aware of the complications who can deal with the complications, a patient who is fully informed of the specific risks, the longevity, the permanence of it, the delayed onset, and that has -- she's tried and failed multiple other options, they have failed, and she is severely symptomatic, in that one, possibly, without arms.

Page 175

Q. So if all of those criteria are met, and let's just assume it's Dr. Goldman, who you know is a reputable and very skilled surgeon in the area of pelvic -- female pelvic reconstructive surgery, okay, let's assume it's Dr. Goldman and all of those criteria are met, if Dr. Goldman implants transvaginal mesh in one of his patients to correct pelvic organ prolapse, is that within the standard of care?

A. I think, if all of the aforementioned criteria, that we won't go over again, assuming that is consistent with this and he has a mesh without arms and Dr. Goldman, again, a highly advanced tertiary care center, thoughtful person, were to consider doing it, I would not criticize him. I would manage the patient differently.

Q. Is this one of those areas, Doctor, that we sometimes see in medicine where there is a lot of debate among physicians who practice in a particular area?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. No. I disagree. I think that -- Tom wants to get his cookie.

MR. CARTMELL: Sorry. I've got to get a piece of my cookie.

MS. GEIST: I can't eat my cookie because I'm

Page 176

talking. That's unfair.

BY THE WITNESS:

A. And I want my cookie, but they'll see crumbs on my face. To answer your question, that's a very, very good question. I think this was a very hot topic in 2005, 2008, that time frame. And then, as the data starts coming out, there was no question -- I will not deny it -- a big wave of surgeons doing transvaginal mesh kits, also a large wave of trainees only learning how to do mesh kits. And the pendulum has swung.

So I -- in meetings now, again, I just got back from a meeting, an international meeting in Stockholm. The SUFU meeting was in February of this year. It's not a discussion point now. There is not an argument. There is no one coming up saying, We've got to do meshes. Meshes are good for prolapse.

Q. So there's not one single solitary doctor that you're aware of who treats women experiencing pelvic organ prolapse who will still use transvaginal mesh?

A. Well, I can't speak for all of the surgeons out there. As far as the ones I know, and I know a few that in the past were very high-volume mesh kit surgeons, they are not presenting data anymore on this and they have changed. I can't speak for everybody out there in the world. I'm saying for the ones that I know

Page 177

at the high level they are not.

Q. But, as we've just discussed even today, with the number of caveats and criteria that you mentioned earlier, there would still be certain patients who would be appropriate candidates for the use of transvaginal mesh?

MR. CARTMELL: Objection. Asked and answered multiple times.

BY THE WITNESS:

A. Okay. With all of those aforementioned, incredibly important screening criteria, there may be a possible -- I disagree with it -- but a possibility of putting a transvaginal mesh without arms. But, again, that's a tiny, tiny fraction of the patients out there.

Q. But they exist, don't they?

A. Well, you're talking about minutia. And -- but, again, in my practice, zero. So I've got -- I've got -- I take care of all of those people with all of those things, multiple reoperations, multiple failures, and I manage them successfully without putting in mesh.

Q. And I understand that, Doctor. We talked about that, but you don't know what percentage. Your only experience, you can't tell me what percentage of those women -- strike that.

You can't tell me what percentage of women who

Page 178

have had mesh implanted, and, in particular, the Avaulta product, actually come to you with complications?

A. We've already gone around that a bunch of times. I do not know the denominator of how many of these were implanted. All I know is what I see at my practice.

Q. Okay. Well, let's -- you mentioned an article to me when we were having this discussion. So let me shift to that for a second. We looked at the Blandon article that was published by the chair of urogynecology at Mayo --

A. No, it wasn't pub- -- no, it was --

Q. -- among -- hold on. You're not letting me finish -- among other colleagues. Do you have something to say about that?

A. Well, it was -- no, that's acceptable.

Q. Okay. I just wanted to see if we had an argument there.

A. No. I mean, in our language, we wouldn't say it was published by the chair because he wasn't the senior author.

Q. Okay. Sorry.

A. That's minor. I'll let you have that.

Q. No. That's fine. That's a fair correction. And the complications that Mayo reviewed at that time

Page 179

was from the 2003 to 2007 time period for patients who were referred to the clinic. And none of those women have had an Avaulta product. You remember that, right?

A. Yeah. And it was -- it was a study -- that's a very good point, because it was January of 2003 through September of 2007.

Q. Right.

A. That's my recollection. Avaulta didn't become available until a couple of months prior to that. So it had -- it would only include two months when the product was on the available list.

Q. Right.

A. So to answer your question, yeah, there are no Avaultas on here because Avaulta was essentially not even available during this time frame.

Q. Well, it was available per the article, itself, right? We talked about that three different times. It's listed right in the article as one of the currently marketed POP products at this time?

A. Incorrect. In 2009 when they submitted it, but this does not include -- this is January of 2003 through September of 2007.

Q. Doctor, my point was, you mentioned the Karram article, I think?

A. Yeah. He was one of the authors. I would be

Page 180

able to get the reference for you here.

Q. That's all right. I think I have it.

A. Abbott. Abbott, et al.

Q. Yeah. There you go. So let's look at that article, because that was a more recent look, right?

A. Correct.

Q. At complications relating to mesh implants?

A. Correct.

Q. And that was what you had mentioned before, right?

A. Yes, I had.

MS. GEIST: Okay. So I just marked this as Exhibit --

THE REPORTER: 5.

MS. GEIST: -- 5 -- thank you, Madam Court Reporter -- to your deposition. Let me hand you that.

(Elliott Deposition Exhibit No. 5 was marked for identification.)

BY MS. GEIST:

Q. Doctor, you don't have to look for it. I just handed you the hard copy.

A. I have my copy that I've reviewed and read.

Q. Well, let me ask you this. You're clicking away on your mouse there and you've got your laptop, right?

Page 181

A. Yes.

Q. So you didn't bring any of those papers with you in hard copy today to your deposition?

A. Well, we're in the electronic era, so I didn't think I had to.

Q. That's very green of you. But my only question is, do you have notes or comments or highlights on these articles?

A. I have highlights, yes.

Q. Do you have any notes or comments?

A. No.

Q. Underlining?

A. We can -- I have highlight. No underlining, but I have highlights. We can go through every single --

Q. Okay.

A. What we could do -- how about this? I'll close this, you close your paper. Let's do it nose to nose on memory. Let's do that.

Q. On memory?

A. Because you are taking away this. This is my data and let's do it.

MR. CARTMELL: Let her ask the questions.

BY MS. GEIST:

Q. Well, Doctor, see, let me explain how the

Page 182

deposition proceeds. I actually get to ask the questions and you get to answer the questions. So I appreciate the offer, but I'm going to decline.

A. That's fine.

Q. Let's -- so you have the paper in front of you with your highlights, correct?

A. Correct.

Q. And this was a review -- well, the paper is entitled, Evaluation and Management of Complications From Synthetic Mesh After Pelvic Reconstructive Surgery: **A Multicenter Study. That was published just last year in 2013, correct?**

A. Correct.

Q. Actually, you know what? I take that back. I have a copy of what is an accepted manuscript that was accepted in October of 2013 by the American Journal of Obstetrics and Gynecology.

A. Yeah. You don't have the final article.

Q. No. Do you?

A. Yeah. I have the final article.

Q. Okay. I'm looking at the accepted manuscript. So you can let me know if anything differs from the final as we go along. But the paper, Doctor, per the objective is to describe the evaluation and management of synthetic mesh-related complications after surgery

Page 183

for stress urinary incontinence and/or pelvic organ prolapse, correct?

A. Correct.

Q. And it was a multicenter retrospective analysis?

A. This was the patient, four patient -- four tertiary care centers.

Q. Okay. We're talking about -- they're looking at referrals of women from four different centers from January 2006 to December 2010, correct?

A. Correct.

Q. How many women that were referred to these centers for complications relating to mesh were implanted with the Avaulta product?

A. From this paper, as far as I recall, they did not know the status of a fairly significant number of the patients, but they do not specifically single out Avaulta.

Q. So this study doesn't tell us anything about the incidence rates or the frequency with which complications occurred in women implanted with the Avaulta products?

A. No. It cannot state the frequency because they don't know the denominator either. This describes the severity of the complications that came into these four select institutions.

Page 184

Q. So we don't know, from the 347 patients reviewed in this study that you mentioned earlier, whether any of them had complications relating from the Avaulta product; is that fair to say?

A. I cannot. Because there are a certain number of patients here that did not -- it was not known what mesh, so I cannot say if Avaulta was there or not, but there was nothing reported on Avaulta.

Q. And we also don't know anything in terms of the incidence rates. We don't know how many patients were implanted with mesh products, during this period of time, who actually experienced these complications?

A. You're talking about all meshes?

Q. Right.

A. No. We do not know. This is, again, just representing the complications that come into these four institutions. So incidence, overall incidence, is not recorded in this study.

Q. That's all I wanted to ask you about that paper, Doctor, if you want to put it aside.

Doctor, I think we talked earlier a little bit about my suggestion to you that you are one of the more outspoken physicians in terms of being anti-mesh in the medical community?

Page 185

A. I would disagree with that. I think there's others out there who are a lot more vocal and adamant against meshes. I'm one of them. I'm not going to deny that.

Q. There has been lots of opinions and discussions in the medical community, as we've just talked about, over the controversy relating to transvaginal mesh, true?

A. Yes.

MR. CARTMELL: Object to the form.

BY MS. GEIST:

Q. Would you agree with me, at least, that your opinions and stance on this issue is one of the more extreme?

A. No.

Q. You wouldn't?

A. Not at all. Absolutely not. In 2005 had I made these statements, then you would have been correct. In 2008, no. They're starting to become the pendulum. In 2011, I'm one of the many. So, no.

Q. You're not -- you're not one of the -- your opinions in 2011 were not extreme in your opinion?

A. No. I don't think so at all. In our national meetings, when we're all together talking about this, I am one of the many. And there are others out there who

Page 186

are tremendously more outspoken than I am. I just happen to have a public forum based upon the institution that I work at.

Q. So you wouldn't agree with me that you are sort of out there and on the fringe and that your opinions are inconsistent with some other physicians practicing in the area of female pelvic reconstructive surgery?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Well, you're putting a lot of qualifiers out there. I can tell you the names of certain very high-profile, high-volume implanters, and we would be at meetings and I would moderate the sessions and we would talk about it. There was a scholarly discourse. There's no anger and there's no, you know, soapboxing. But I was -- I was -- again, if I did it in 2005, I would agree with you. Not now.

Q. Not in 2011 either?

A. No, not at all. I'm at these meetings. That's what I do for a living all over the world.

Q. So your opinions back in 2011 were consistent with the leading physicians practicing in this area and with the medical organizations representing physicians who practice in the area of female pelvic reconstructive surgery?

Page 187

A. Speaking within the confines of female urology --

Q. Right.

A. -- and the circle that I --

Q. That's what we're talking about, right?

A. In very, very high-profile female urologists, Shlomo Raz, arguably one of the bigger and better ones, Gerry Blaivas, oh, Greg Bales, University of Chicago, all of these types, no. We're -- this was a consistent, you know -- Philippe Zimmerman. Philippe Zimmerman, if you want somebody who is vocal, Philippe Zimmerman is. I've tried to retain a balance. And I have a problem. I'm taking care of women whose lives have been destroyed by a product and I'm trying to do something that's good for them.

(Elliott Deposition Exhibit No. 6 was marked for identification.)

BY MS. GEIST:

Q. Doctor, let me hand you what I've marked as Exhibit 6 to your deposition. I'm sorry to throw it at you. I'm not really meaning to throw it at you.

MR. CARTMELL: That's all right.

BY MS. GEIST:

Q. Do you have that in front of you, Doctor?

Page 188

A. Yes, I do. It's the AUGS report on surgical treatments.

Q. All right. And you're -- you're familiar with this, I'm sure?

A. Yes.

Q. Correct?

A. Yes, I am.

Q. And you're a member of AUGS, which is shorthand for the American Urogynecologic Society, correct?

A. I believe I am, yes. I have to look at my CV.

Q. Do you know?

A. I'm almost convinced I am, but I'm a member of the International Urogyn Society and AUG or AUGS, SUFU, so I'd have to say, yes, I am.

Q. Okay. And AUGS, as indicated in the paper, is a nonprofit organization of thousands of physicians who specialize in treating pelvic floor disorders?

A. Yeah. That would be fair to say.

Q. So this is an organization for -- of health care providers, doctors. There's no lawyers in this organization, correct?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

Page 189

A. I can't speak to that, no.

Q. You're not aware that there's any, right? I mean, these are doctors looking for the best things for women who are experiencing pelvic organ prolapse, correct?

MR. CARTMELL: Object to the form.

BY MS. GEIST:

Q. That's what the purpose of the organization is?

MR. CARTMELL: Object to form.

BY THE WITNESS:

A. Yeah. But as far as lawyer involvement, a lawyer reviewed this. They reviewed the ones for SUFU, so they reviewed this, I'm sure.

Q. Okay. Well, this was -- this paper was put out as a physician statement by AUGS in response to the FDA safety communication in 2011, correct?

A. That is correct.

Q. So after FDA came out in 2011 and made a statement relating to transvaginal mesh for the use in POP, this group of physicians put out a position statement and response. Fair summary?

A. That is correct.

Q. And if you look with me on the third paragraph, the position statement says, The American

Page 190

Urogynecologic Society strongly opposes any restrictions by state or local medical organizations, health care systems, or insurance companies which ban currently available surgical options performed by qualified and credentialed surgeons on appropriately informed patients with pelvic floor disorders?

A. That's what it states, yes.

Q. Do you agree with that position?

A. There are a lot of caveats in here. Number one, appropriately informed patients. If the patients aren't appropriately informed, the IFUs are incomplete, they can't be appropriately informed. So you have to assume, then, they have received all of the appropriate information. Qualified and credentialed. Credentialed means nothing. Qualified, okay. If you want to go on qualified, you're going to have to have high-volume, tertiary center individuals. So subsequently it's eliminated almost all of the private practice doctors from that group there.

So -- and then I disagree as far as state and local medical organizations and health care systems and insurance companies getting involved. This is for the betterment of women. This is a women's rights issue. Women are being hurt by this product. I would want those organizations to have at least take a look.

Page 191

Q. Well --

A. And a healthy discourse and looking at this is not wrong.

Q. I --

A. Okay. Go ahead.

Q. Sorry. Were you finished?

MR. CARTMELL: Were you done?

BY MS. GEIST:

Q. I didn't want to interrupt you, Doctor. We had that issue earlier. Go ahead.

A. No. I think this is -- there are -- I cannot fully agree or fully disagree with this. But you can't, as a blanket statement, say one or the other. Now, I'm done.

Q. Okay. So I actually agree with you on one of the things you said, that this is a women's right -- rights issue, Doctor. So do you agree with the other statements in this paper beginning on page 2?

MR. CARTMELL: Take your time and look at it if you need to.

BY MS. GEIST:

Q. At the top, that a ban on alternative surgical treatment interferes with the patient/physician relationship and withholds FDA-acceptable options that the patient and her physician may decide is the best treatment option for her particular clinical situation. Do you agree with that?

Page 192

A. To a certain extent, I do. If the physicians involved and medical organizations involved are not appropriately policing themselves and women are being permanently damaged sexually and physically, and I'm the one picking up the pieces, I disagree with this.

I think that a ban, at the minimum, is the most appropriate thing until appropriate studies show that it's safe and that the benefits outweigh the risks. Currently, the risks far outweigh the benefits and that's a testament to what I see every day in my clinic.

Q. So when you say the risks out see the benefits, the risks of what in particular?

A. Okay. That is an excellent question.

Q. Thank you.

A. Number one -- I didn't mean that to be sarcastic. I'm saying that is actually a good question.

Q. No. And I was thanking you legitimately. Go ahead.

A. Okay. Pelvic organ prolapse and stress incontinence, but let's just deal with pelvic organ prolapse, is a quality-of-life issue. It does not kill patients. Okay. In all of my years, I've never -- well, there's been one patient in California that had erosion infection, but that's a unique situation.

Page 193

For the vast majority, it's quality of life. They come in with a sense of fullness, pressure, falling out, as we have covered very well before. They then get this procedure, and these women's lives, they are -- not just them, but their partner and their family, their children, their grandchildren, their parents, their lives are destroyed because this woman can't sit. She can't -- she can lie down sometimes, can't stand.

So extreme views on severe damage and risks versus benefit? Take somebody with a quality-of-life issue and give them a permanent disability, the risk outweighs the benefit. If we have an individual who had a heart problem and there's some type of valve and they're going to die without it, a different ball game. But we're not. We're talking quality of life.

Q. All right. So let me try and break it down a little bit. When we were talking about risks, you just gave me a very long answer, which I appreciate, but I would like to focus a little bit on what we're talking about. Are we talking about pelvic pain, dyspareunia, and erosion? Are those the three main risks that you say are unreasonably high with respect to transvaginal mesh?

A. No. I'm talking about the severity and the

Page 194

frequency of pain, the location of the pain, buttock pain, obturator foramen pain, vaginal vault pain, adductor and abductor, A-B-D-U-C-T-O-R, and then, A-D-D-U-C-T-O-R, thigh pain, the mesh extrusion, the mesh erosion, the granulation tissue, chronic vaginal discharge, chronic inflammatory process, foreign body reaction, chronic severe debilitating vaginal pain, chronic severe debilitating pelvic pain, pain for the sexual partner, and a lifelong risk of this, and, very importantly, advanced level of complications requiring advanced level of surgeons to try and fix.

Q. All right. So hold on a second.

MR. CARTMELL: Were you done?

THE WITNESS: Yes, I am.

BY MS. GEIST:

Q. So we're talking about pain. You're not going to dispute, are you, Doctor, that the pain you just described, all of the different types of pain you just described, may be experienced by a woman who has had a native tissue repair, or an ASC, to treat her pelvic organ prolapse? That is a known and well-established side effect in the literature for either one of those procedures, true?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

Page 195

A. I disagree, because we are -- we have to put qualifiers in there. In my 25 years of medical experience going back to medical school and OB/GYN, which was all native back then, my surgery training at a high-volume tertiary care center, advanced level training, I have never once seen the severe -- the severity of the location of the pain and the irreversibility of it and the ability for us not to be able to fix in the native transplants.

Q. Well, and what about -- what about dyspareunia, in particular?

A. As I'm --

Q. Dyspareunia, in particular, I'm sure you're not going to disagree with me, is a known and well-established side effect with a native tissue repair or an ASC or even a laparoscopically performed sacrocolpopexy, true?

A. Okay. I disagree because you have to put on with the qualifiers of the severity, the delayed onset, the ability to fix it. Remember, I mentioned, in my series, which I've watched very closely, I've had one patient who had severe dyspareunia after an anterior colporrhaphy. But we were able to cut the suture and the pain went away. But compare that to all of the other patients that I had with pelvic pain after mesh, I

Page 196

can't even remotely fix. I'm done.

Q. Okay. Thank you. I was just going to ask you. All right. So let me see where we agree and where we don't agree. Okay.

A woman has a potential complication or side effect with pain with either native tissue, ASC, or transvaginal mesh. But it's your opinion that the pain is more significant or more severe with the mesh versus the other procedures. Did I get that right?

A. Correct. And different onset and different location.

Q. Okay. Same things with dyspareunia, a woman has a risk of a potential complication or adverse event of dyspareunia if she's had a native tissue repair or an ASC repair for her prolapse, but it's your opinion that the dyspareunia with transvaginal mesh is, what, more significant?

A. Severe, relenting, progressive, and destroying of women's lives.

Q. Okay. Same side effects and complications, but the severity is the difference among these different procedures. Is that what you're telling me?

A. No. I disagree as far as with using the word same. These are not the same. This is what I do on a daily basis. And I see these women who can't even sit

Page 197

down on my exam table. Not on my exam table, on the chair because of the severity of pain. I have never once seen that with a native repair. That's my own and the others coming in referred to me.

Q. Okay.

A. And if I'm at a tertiary care center, arguably one of the biggest volumes in the United States, and I have not seen one patient sent in to me with a native repair problem, but I see five a day of the other ones, we're talking a different type of problem.

Q. Well, Doctor, you've said a couple of times you're referring back to your own experience with your patients at the Mayo Clinic, correct?

A. No. That's not -- well, yes and no with that. I'm referring to my experience in the ones that I've seen. But, remember, I'm a referral center. So I'm getting patients from all over the United States sent in to me. And if transvaginal native repair problems, we're having all of these problems, I would be seeing them, but I'm not seeing them.

Q. So I just want to explore the basis for the opinions you just gave on -- relating to pain and dyspareunia. All right. I also want to talk about erosion a little bit.

Doctor, let me start with dyspareunia. Okay.

Page 198

It's your opinion that women who have had transvaginal mesh experience greater dyspareunia than women who have had their prolapse repaired via another surgical procedure; is that a fair summary?

A. I'm saying there's a qualitative difference and a location difference, and that goes along with severity and frequency.

MS. GEIST: I'm not doing this very well. So the record is clear, I'm talking about the exhibit marker.

(Elliott Deposition Exhibit No. 7 was marked for identification.)

BY MS. GEIST:

Q. Dr. Elliott, let me hand you what I've marked as Exhibit 7. Again, I'm sorry, I'm not really trying to throw it at you, but the table is kind of long.

Dr. Elliott, for the record, Exhibit 7 is an article entitled, Incidence and Management of Graft Erosion, Wound Granulation, and Dyspareunia Following Vaginal Prolapse Repair With Graft Materials: Systematic Review?

A. Correct.

Q. Do you see that, Doctor?

A. Yes, I do.

Q. And this was published in 2011 by Dr. Abed and others for the symptomatic review group for the Society

Page 199

of Gynecologic Surgeons?

A. Correct.

Q. Is that correct?

A. Correct. For the International Urogyn Journal, which I'm a reviewer for.

Q. Did you review this paper in particular?

A. I don't recall doing that one, this one, no.

Q. And, as you can see, either in the abstract or the introduction, the purpose of this study was to describe the incidence of graft erosion, wound granulation, and dyspareunia with adverse events following vaginal repair. Do you see that?

A. Yeah, from 1950 to 2010.

Q. That's the time period for the review of reports --

A. Yeah, so 55 --

Q. -- on these types of adverse events, correct?

A. Yeah. So 55 years of this is not considered involvement with the mesh kits.

Q. I'm sorry?

A. 55 years of this paper of the 60 total are not involving the mesh kits.

Q. Correct. But the paper went through and looked at adverse events reported in Medline articles through November 2010, correct?

Page 200

A. Yeah. But they're put --

Q. Okay. Hold on.

A. But you asked me -- no, you asked me a question, though.

Q. Sorry. I wasn't finished.

A. You said correct, and correct means I'm supposed to respond.

Q. Okay. You know what? Point -- point to you. Go ahead and respond.

A. Okay. But, also, they're looking at from 1950 to 2005 a lot of other horrible products were put in women's vaginas; Gortex, various other things, cotton, all of that type of stuff. So it's not exactly -- we're not comparing apples to apples. I've made my peace. You can go ahead.

Q. Okay. Well, the study -- the study results concluded that dyspareunia, which is pain during vaginal intercourse, correct?

A. Correct.

Q. Okay. That was described in 7 -- 70, pardon me. Dyspareunia was described in 70 of the studies that were included in the systematic review, correct?

A. I don't see where you are, but I'll take your word for it.

Q. I'm at the top --

Page 201

A. In the abstract.

Q. Yeah.

A. Under Conclusions.

Q. It's above Conclusions. It says, Dyspareunia was described in 70 studies.

A. Oh, here we go.

Q. Do you see that?

A. Yes. It was described in 70 studies for a rate of 9.1 percent, correct.

Q. And dyspareunia was reported both in pelvic organ prolapse repair surgeries and involved both synthetic and biologic mesh, correct?

A. That's what it states, yeah.

Q. And the rate -- the incidence rate or the reports of dyspareunia were greater in the women who had had a biological implant or biological graft used in the tissue repair versus the synthetic?

A. That's what the results are quoting from 1950 to 2010. They're talking about those biologicals being at a slightly higher rate. I don't know if it was statistically significant, though.

Q. Well, statistically significant or not, you can see that the -- there were 8.9 -- 8.9 percent reported dyspareunia when using -- when having -- when having a synthetic versus 9.6 for biologic graft. Do

Page 202

you see that?
A. I see it. But I think, for the record, we want to come on the record that you are stating statistical significance is not important. Is that what you're saying?
Q. You can ignore that. I'm just saying, if you look at the -- you can ignore my statement about statistical significance.
A. Okay. Then it's back on the playing field then, so this could just be by chance. We'd have to go in the paper and find out statistically significant. Regardless, it's still showing nearly 90 percent of the synthetics had problems, dyspareunia. It's still high.
Q. But not any higher than the biologic grafts used to treat pelvic organ prolapse, true?
A. Well, with biologics there's SIS, there's cadaveric tissue, there's porcine dermis. You know, that's immaterial comparing it to those. These aren't comparing it to natives, native repairs.
Q. No. This is -- this is comparing the use of a biologic versus a synthetic --
A. Okay. Then what --
Q. -- graft, correct?
A. I'm sorry. Yes. And what I will go on the record as agreeing with you that the synthetic in this,

Page 203

whether it's statistical or not, is 0.7 percent less bad than biologics. It's still bad. It's just less bad than the biologics.
Q. All right. You can put that one aside. Let me show you --
MR. CARTMELL: Keep going.
BY MS. GEIST:
Q. Let me show you, Doctor, what we'll mark as Exhibit 8 to your deposition.
(Elliott Deposition Exhibit No. 8 was marked for identification.)
BY MS. GEIST:
Q. Let me hand that to you. Now, this study, to your point, Doctor, actually looked at trocar-guided vaginal mesh compared with conventional or native tissue repair, correct? And, just for the record, this is the Withagen 2011 study entitled, Trocar-Guided Mesh Compared With Conventional Vaginal Repair and Recurrent Prolapse?
A. Yeah. It's Withagen. He's Dutch.
Q. Withagen. Thank you for that correction. Are you looking for the paper on your laptop?
A. I have it. I have it right here. We can go through it again. It's highlighted. I've read it.
Q. Okay. Good. So you read this one?

Page 204

A. Yes.
Q. And this is on your reliance list, right?
A. Correct. And there are no notes. This is just highlighted.
Q. And this study concludes, does it not, Doctor, that vaginal mesh was introduced due to the high failure rates or recurrence rates seen in native tissue repairs?
A. Yeah, but they're based upon that, their submission in 2011, which means, you know, earlier than that, on the anatomic and the perceived. This is somewhat the old era of thinking.
Q. Well, this study, you say it's the old era of thinking, Doctor, but this study looks at not just anatomic success, but it also looks at quality-of-life issues, does it not?
A. Correct. It does.
Q. Because it looks at dyspareunia in particular, right?
A. I'd have to look and see if it did. I would suspect it would talk about it, but I would have to find it.
Q. Okay. Well, let's talk about -- let's talk about anatomic failure or success rates first. Okay. Is that all right with you, Dr. Elliot?
A. That's fine. Sure.

Page 205

Q. Okay. Well, this -- this study looked at essentially where a woman -- where women were at 12 months after either having a native tissue repair or a transvaginal mesh repair, right?
A. Correct. I wanted to see which type of repair they did. Withagen usually uses Prolift, which is a different product. Yeah. They're using Prolift. So that's a different -- when we talked about it before, that's a different product than what we're talking about with Avaulta; different arms, collagen, density, high density, those types of things. But, yes, that is -- that is --
Q. It's still -- it's transvaginal mesh, though, right?
A. Yeah. But before you didn't let me talk about these types of papers when we were talking about Avaulta. So now we're going to accept this data and correlate it to Avaulta.
Q. Well, we're talking about trocar-guided transvaginal mesh, right?
A. Okay. Good. So now -- all right. That's fine.
Q. Hold on. That is one of your criticisms of the Avaulta product, which is why I brought out this paper, true?

A. Yes, but we didn't bring it out earlier when I was trying to bring them out. So we're not being consistent.

Q. Okay. Well --

MR. CARTMELL: For the record, we're talking about Avaulta products.

BY MS. GEIST:

Q. Well, my bad. I brought it out now. But the point is, Doctor, it's talking about -- it's looking at and comparing not just the success of women who have undergone a transvaginal mesh procedure, a trocar-guided transvaginal mesh procedure, but also looking at quality of life issues, correct?

A. That is what it's doing, yeah.

Q. And the authors of this paper found that there was a 45.2 percent anatomic failure rate in the native tissue group after 12 months compared to a 9.6 percent failure rate in the mesh group after 12 months. Is that what they found in their study?

A. That is what they stated, and that's why I earlier stated we're treating symptoms, not anatomy.

Q. And we'll get -- we'll get to that, Doctor?

A. Oh, I don't have a guarantee we will, but go ahead.

Q. We will. And this -- so, based on this study,

Doctor, the women who proceeded with a native tissue repair were five times more likely to have an anatomic failure after surgery, correct?

A. Yes.

Q. In other words, a recurrence of the prolapse that they wanted to fix in the first instance, five times more likely in the native tissue group. Isn't that what this study tells us?

A. It tells us that and that 80 percent were happy just saying equal. So they were both happy in each group.

Q. And we got five times more failure rate in the native tissue, correct?

A. You're right. And then what I stated very, very clearly, the majority of the time women don't care about their anatomic success. They care about are their symptoms relieved.

Q. Well, and let's go -- let's go to that right now because I know that's what you want to talk about, and I want to talk about it, too. So dyspareunia is one of the problems we've been discussing today, right?

A. Correct.

Q. And Withagen's paper or study looked specifically at dyspareunia reports of the women who had both a trocar-guided transvaginal mesh inserted and

women who underwent the native tissue repair, right?

A. Correct.

Q. And the paper concluded that the difference in reported dyspareunia between groups was not significant at the 12-month period, correct?

(Exit Mr. Jeffrey Kuntz.)

BY THE WITNESS:

A. And that is a very good point, also, yes. At 12 months, 51 of 97, 53 percent of the conventional group and 53 of 93, 57 percent were sexually active and the dyspareunias were equal at 12 months. However, we know, from Klosterhalfen and others, mesh degradation continues up to 15 years. So one-year data does not help us out. However, to agree with you, that is their findings at 12 months with the Prolift.

Q. Okay. And at 12 months we also know that there were reports of de novo dyspareunia in both groups, correct? In other words, de novo dyspareunia means brand-new dyspareunia, did not -- did not exist prior to the surgery? That's what de novo dyspareunia means, correct?

A. No. I'm familiar with what de novo means.

Q. Well, I'm doing this for the purposes of the jury and the lay people trying to understand this stuff.

A. Sure. Yes. At 12 months, which I've

reiterated is -- or should reiterate is insufficient because this is not 15 years on down the road. But three out of 29, in the conventional 10 percent, and three out of 37, 8 percent in the tension-free. So I would -- statistically, those are going to be identical.

Q. Statistically identical. But, specifically, as you've just said, 8 percent of women in the mesh group reported de novo dyspareunia and 10 percent of the women in the native tissue group reported de novo dyspareunia, true?

A. Possibly, because, unfortunately, they did not give us qualifiers on the severity of this pain. They're stating pain, yes or no. It's like being pregnant, yes or no, at three months is different than at nine months. Okay. So, yes, this is what they stated at 12 months without any qualifiers.

Q. Okay. The reports of dyspareunia, in both groups, native tissue and trocar-guided transvaginal mesh, were statistically the same at 12 months, correct?

A. I will agree with you as you state it, that at 12 months; but, again, that has no qualifier on the severity.

Q. Well, we don't know from the study, and I'm sure -- I'm sure you wouldn't guess, Doctor, that there was any difference in the severity, right?

Page 210

A. Absolutely, I would. Most questionnaires, if you look at most studies, again, that's what I do for a living. They're insufficient. And all they're saying is, do you have sexual discomfort; yes, no? That is nothing on the qualifier and the severity of it.

Q. All right. But you have no basis, based on this study, to say that the women in the mesh group had more significant dyspareunia than the women in the native tissue group, true?

A. Well, with the Prolift product here -- I'm not talking about Avaulta. So, really, this is kind of a moot point to talk about this. In this study, they do not give us those qualifiers. However, that is inaccurate to say I don't have data to support that has it higher from other studies that look at it with a Visual Analog Scale and the severity of the pain.

So if we're going to start talking about lots of papers -- let's go to the totality of knowledge out there -- many papers talk about the severity of mesh pain. My personal experience taking care of patients daily talk about the severity. So, in this study, they do not give us qualifiers to know the severity.

Q. So is that -- is that your criticism of Withagen, that there's no qualifiers with respect to the dyspareunia severity?

Page 211

MR. CARTMELL: Other than the other things he's told you?

MS. GEIST: Well, sure.

BY THE WITNESS:

A. Well, that would be one of them. And Mark Vierhout I happen to know. I was just with him in a meeting. And these are the things that we talk about, that, when we look at studies and really do good metaanalysis of studies, most of them are deficient and this would be a deficiency. It doesn't mean it's a worthless paper, but there's deficiencies.

Q. I just want to understand your reasons for not finding this paper reliable, in your view, in terms of the incidence rates of dyspareunia among mesh-implanted patients versus native tissue repair.

A. Well, that somewhat misstates my statement here or misstates what I said. I didn't say it was unreliable. I said it's in- -- it's insufficient, short, not enough -- not enough follow-up, a different product -- Prolift, not Avaulta -- and what they don't give me is the severity of this pain. There's no Visual Analog Scale. There's no quality-of-life survey relative to sexual discomfort.

Q. But you don't know, and I don't want to belabor the point, but you don't know from this study that the pain was any different in the mesh group versus the native tissue group?

Page 212

A. The authors do not provide us with enough data. Had I reviewed this, I'd say we need to know that data.

Q. Okay. But you can't? I mean, you're not going to guess, I assume, right, Doctor? You're not going to guess and just assume that the pain in the mesh group was greater than the pain in the native tissue group? You wouldn't do that, would you?

A. I'm not in the ball game of guessing. And based upon my experience, it would be worse. And what's it going to be five years from now, and that is worse.

Q. Well, we don't know that, though. There is no -- there is no reanalysis of this data. There is no update by Withagen and the other authors looking at what happened over the next -- I think you said five years, but the paper was in 2011, so three years.

We don't know that there is any change or difference in the incident rates of dyspareunia in the mesh group versus the native tissue group, do we?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Well, we do know from the other literature out there. Again, I keep going back to Klosterhalfen

Page 213

because it's a good one, but there's others. Degradation, contraction of the mesh is progressive. Klosterhalfen gave us up to 15 years. This is one year in time. So all I'll agree with is what the authors have stated here with my points that there is insufficiency -- insufficiencies of this paper.

Q. That's fine. And, by the way, we'll talk about degradation shortly. But are you -- are you telling me that you believe that mesh degradation is directly attributable to dyspareunia?

A. Yes.

Q. Polypropylene degradation results in dyspareunia?

A. It can, yes. Definitely. That is one of the cascades of the process to cause dyspareunia and scarring.

Q. And this is your opinion, Doctor, even while you still implant polypropylene mesh in your patients today?

A. That is -- that is an unfair statement. I am not putting in mesh kits with mesh arms that fold and saw the tissues and are contaminated with bacteria and candida species from the vagina. I'm putting it in sterilely, lying it flat on the abdomen -- excuse me, in the vagina, in sterile positions, suturing it down so it

lays flat, and analyzing those patients over 12, 15 years -- excuse me -- 13 years and not finding the problem.

Q. So degradation of polypropylene mesh doesn't occur unless it's a four-armed product; is that what you're telling me?

A. No.

Q. So explain to me what you're talking about when you say degradation of polypropylene.

A. Okay. That's outlined specifically in my notes, in my expert report. I mean, we are looking at the confluence of multiple different factors of transvaginal, contaminated mesh, plus or minus collagen on it, which impairs healing, torquing on this to go through the obturator foramen, rolling of the mesh arms, having them scar in place through the buttock muscles, the adductor muscles of the thigh, and that process is different than what I'm saying that occurs through the abdominal route. Those are completely separate surgeries.

Q. So mesh implanted via the abdominal route doesn't have any risk of degradation?

A. No. I would say it probably does degradate (sic) to a certain extent. Polypropylene is polypropylene no matter where it's put in the body.

However, there are multiple different factors. Polypropylene is put in for inguinal hernia repairs. It's put in the thoracic cavity. It's put in the eye and it's put in for sacrocolpopexies.

Q. And --

A. That's different than transvaginal.

Q. And polypropylene, I assume you would agree with me, is a well-established material that is safe for implantation in the human body, true?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. That's too broad. If it's for inguinal hernias where there is no other treatment option, or thoracic wall hernias where there's no treatment option, I would say that is an acceptable risk-versus-benefit ratio. But, as we keep going back to, putting it through the vagina, a contaminated, lactobacillus, candida, et cetera, torquing on the arms, rolling on the arms, sawing back and forth, then, no.

Q. What does sawing and torquing and the other things you just said have to do with degradation?

A. A huge amount to do with degradation, okay. Because degradation occurs in the presence of inflammation and with bacterial contamination. The

greater the inflammatory process, the greater the rolling of the mesh; the greater the inflammation, the greater the release of peroxides, free radicals, the oxidation process starts, the mesh starts to degrade. The more the mesh degrades, the more the increased inflammation, subsequently pain. Pain happens down the vagina. And as it goes around the obturator foramen, it gets rock hard and it hurts like crazy and you can't get it out.

Q. Okay. Doctor, thank you for that. We're going to go back to degradation, but I want to finish up on some of these other topics we started exploring. in particular, dyspareunia. Did -- in reaching your opinions, did you look at the Carey study?

A. Yes. It depends which one you're talking about. He's been fairly prolific.

Q. Agreed. I'm marking it as Exhibit 9.

(Elliott Deposition Exhibit No. 9 was marked for identification.)

BY THE WITNESS:

A. Vaginal Repair With Mesh Versus Colporrhaphy For Prolapse?

Q. Correct.

A. Okay.

(Enter Mr. Jeffrey Kuntz.)

BY MS. GEIST:

Q. This is another study, Doctor, again comparing both anatomic success of transvaginal mesh versus native tissue repair and also looking at quality of life issues, to your point, right?

A. Well, all they state their objective is to compare vaginal repairs with mesh and traditional with the prolapse. This is not an Avaulta study.

Q. And, in this study, Doctor, first starting with anatomic success, 81 percent of the women in the mesh group achieved anatomic success after 12 months and 65 percent of the women in the native tissue group had anatomic success at the 12-month period, correct?

(Exit Ms. Ann Gayle.)

BY THE WITNESS:

A. Which was not statistically significant. So, in other words, based upon statistics, they're identical. So there were no difference.

Q. Okay. So the mesh was certainly -- looking at statistical significance, the mesh was certainly no worse, in terms of anatomic success, in this study than native tissue, correct?

A. All you can say with this is it was an underpowered study, they didn't have enough patients in

Page 218

it, and that, based upon this, statistically they were equal.

Q. And, in terms of dyspareunia, do you have highlights on this study, too, Doctor?

A. Yes, I do.

Q. All right. In terms of dyspareunia, the same exact number of women reported de novo dyspareunia at the 12-month period, correct?

A. That is correct, limiting it to 12 months with the Prolift. I imagine this is Prolift. Carey usually writes about Prolift. That is what the findings were at 12 months.

Q. And even though it's the same number of women, the incidence rate was actually higher in the native tissue group, correct?

A. Yes, but statistically insignificant.

Q. Okay. But still higher?

A. But statistically insignificant.

Q. But still higher, right? Yes?

A. The percentages that they had were statistically identical.

Q. 16.7 in the mesh group, 15.2 in the native tissue group, correct?

A. That is what they state in this study.

Q. And --

Page 219

A. Which were statistically insignificant.

Q. And, again, because this study looked at only a 12-month period after the surgeries, you don't find this study to be reliable in terms of the comparative incident rates of dyspareunia in women having native tissue repair versus mesh repair?

A. No. I think that -- I think this is an important study, but there's limits to it. It's under -- underpowered, meaning insufficient number of patients, and not statistically different at 12 months.

Q. But like the Withagen study, Doctor, you would agree with me, if you look at both of these studies, both of these studies indicate that the dyspareunia reports from women in the mesh group and the native tissue group were the same?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. For the Prolift product, which does not have the ultra-dense, high-density arms, does not have collagen, at 12 months, they were statistically the same.

Q. What -- the Avaulta product, the Avaulta Plus product, has collagen, correct?

A. That is correct.

Q. The other Avaulta products do not, correct?

Page 220

A. I'm un- -- I don't -- no, I never heard of them being on there. The Solo does not have it.

Q. Right. So you think that there might be a difference between this product and the Solo based on density?

A. I didn't say that.

Q. What did you say?

A. Excuse me. Yes, I did say that.

Q. I thought you said density made the difference.

A. The arms of the Avaulta products are heavyweight at, what, 95 grams-per-meter-squared compared to the Prolift, which I believe was right around 45 or so. I could be off on those numbers, but that and in addition with the Plus having the collagen.

Q. All right. Let's set aside the collagen for a second. All right. Let's just talk about the Solo, which doesn't have collagen. Okay.

(Enter Ms. Ann Gayle.)

BY MS. GEIST:

Q. You think the reason why this study outcome would be different for Avaulta is because of the arms density of the product?

A. Yes. And that not having a plastic sheath over it causing you to saw through the tissues because

Page 221

both of those have to come into play.

Q. What studies do you rely on for your opinion that the arms' density would have a greater impact on dyspareunia rates?

A. Okay. I'm going to go to my expert report. I talk through the density -- that's on page 21 -- where the biggest studies I'd be quoting would be -- the classic one would be Cobb, et al., talking about the higher density, having more reaction, more inflammatory response. Inflammatory response leads to degradation. Degradation leads to increased inflammation, which leads to scarring, which leads to incorporation of nerve tissue and leads to pain.

Q. So we've got to make -- what did you just give me, like five hops until we get to dyspareunia?

A. The body --

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Yeah. That is an incredible oversimplification. If I were to cut my hand, there is a cascade of clotting. There is like 12 different steps. Things in the body lead to other things. It's not just in isolation. You just don't have degradation. That's it. It's a process and then you have to throw in there the rolling of the arm, which then decreases the

pore size, which then increases the inflammation. So, yeah, there's multiple steps. It's complicated, but it's logical.

Q. Is there any study that actually looked at the density of the arms and different products and looked at the resulting dyspareunia rates?

A. Worded that way, I can't think of a study off the top of my head right now looking at that implement -- implantation.

Q. Let's -- since we're having such fun with these studies, let's look at another one on dyspareunia. Did you look at Nieminen --

A. Yeah.

Q. -- Nieminen when you formed your opinions, Doctor?

A. Yes, I did. He has multiple papers, so it's --

Q. Yep. So I'm looking at the 2010 one, and I think we're up to Exhibit 9.

MR. CARTMELL: I think we're at 10.

MS. GEIST: We're at 10?

MR. CARTMELL: Yeah.

MS. GEIST: I apologize.

THE REPORTER: We were going too fast. I missed it.

(Elliott Deposition Exhibit No. 10 was marked for identification.)

BY MS. GEIST:

Q. Okay. Dr. Elliott, I'm handing you what we've marked as Exhibit 10 to your deposition, a copy for counsel. And, as I stated to you, this is the Nieminen, N-I-E-M-I-N-E-N, study published in 2010 entitled, Outcomes After Anterior Vaginal Wall Repair With Mesh: **A Randomized Controlled Trial With a Three-Year Follow-Up.**

So I think, Doctor, some of the criticisms you've stated to me earlier about some of the other studies you looked at, the Withagen and the Carey study, was that they only looked at what was going on with women after 12 months, right?

A. Short-term.

Q. Right. Too early. This study looks at what was going on with women after three years, right?

A. They have it at 36 months. I don't know how many patients made it that far.

Q. Okay. So 36 months is three years. We don't have a disagreement there?

A. No. We don't, unless I need to know how many patients made it. That's the mean follow-up or if they -- what the variance is with that.

Q. Okay.

A. But they say at three years follow-up.

Q. Yeah.

A. Which is still short-term.

Q. It's a lot longer than the 12-month studies we looked at. Fair?

A. I disagree. If you put this in a 40-year-old woman who is going to live 40 years, three years is insufficient.

Q. Okay. So you don't like this study either because it's insufficient in terms of time period after surgery to see what's going on?

A. No. I'm saying it's definitely an improvement, but we have a permanent device to go into women and three years is, in this big spectrum of things, very small follow-up.

Q. Well, this study established that three years after, there was a 41 percent recurrence of prolapse in the native tissue group versus a 13 percent recurrence of prolapse in the mesh group, correct?

A. That's what they state, and we'd have to then find out how many of those were symptomatic with it. But that's what they state.

Q. All right. But, again, this is the third study we've looked at together where anatomically mesh

was clearly better than native tissue --

A. No.

Q. -- in repairing the defect, right?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. I'm sorry, no. That second one we looked at was statistically insignificant, okay, because it was an underpowered study. I would have to look at -- now, this has a P value showing that anatomically these women had the percentages that you referenced with anatomic improvement that, again, we are treating a quality-of-life problem. So we treat the subjective, not necessarily the anatomy.

Q. And I hear you, Doctor, and this study looked at exactly that. Like the other studies we looked at, it looked at quality of life issues. The study looked at dyspareunia in particular. One of the main issues we've been talking about; so did this study. And this study also looked at the feeling of vaginal bulge as well, which is another symptom of prolapse, true?

A. Correct.

Q. So, in this study, the authors concluded that there was no difference in the reporting of dyspareunia in the mesh group versus the native tissue group?

A. Had I reviewed this record, I would have said,

How can you have 19 percent of the women have a mesh extrusion and not have dyspareunia? Because it's like barbed wire in there, so either the patient or spouse is going to have it. So you're saying that -- so I would say there's a major issue that they'd have to address. What happened to those patients? So this would be something that I would write the authors about if I were doing a review.

Q. All right. So you'd have some questions --

A. Their data does not jive.

Q. I'm sorry. You have some questions or you're critical of the data in this study, right?

A. No, I didn't say I was critical of. I was saying there are issues that would have to be resolved. I would say these would be questions that would pop up at meetings, those types of things. And this was from April of 2003 to 2005. So, again, we're talking about a different product. Again, we're probably -- I don't know what product they would put in there. I don't even know if it has arms in it either.

Q. Well, actually four-armed mesh products were used in this study, Doctor.

A. Okay. Manufactured by who, what was the pore size, what was the weight size, all of those types of issues. So that would be important to know. And I'm

going through the materials and methods. And it's in Finland, so who knows what they have there in their health system.

No. Here we go. There -- it's a 6-by-11 patch. I don't see anything about arms. Oh, here we go, self-tailored arms.

Q. Four arms, do you see it on page --

A. Yes. It's on 235.e.3. I see it.

Q. Right. Okay. So we can agree it's a monofilament polypropylene four-armed mesh used in the mesh group, correct?

A. Correct.

Q. And this study, at least, in 2010, tells us that the dyspareunia reports in the mesh group versus the native tissue group were the same at the three-year period?

A. That was the findings of this study at that time, yes.

Q. Okay. Well -- and you say at that time. I mean, there was no update or reanalysis of this study that you're aware of, is there?

A. And that is one of the major faults in these studies. They don't follow up on the patients. So, in this study, at three years, with a nonBard product, that was the results they had.

Q. Okay. But it's another one of those awful four-armed products you're talking about, right?

MR. CARTMELL: Object to the form.

BY MS. GEIST:

Q. It's a four-armed polypropylene mesh product similar to the Avaulta product, true?

A. No. I can't say that. I don't know the weight of this.

Q. Okay. But it is four-armed and it's polypropylene, right?

A. Correct. They have a self-tailored, four-armed light they call it. So we don't know the arm lengths. As we've mentioned, it makes a big deal --

Q. Well --

A. -- if those arms are thick and heavy.

Q. -- you keep saying the arms are thick and heavy with the Avaulta product. Isn't the Avaulta product classified as Type 1, lightweight, monofilament, macroporous mesh?

MR. CARTMELL: Object to the form.

BY MS. GEIST:

Q. Are they not?

A. You're using the Abed rating system from 1997.

Q. Well, it's still in effect, is it not?

A. No, it is not. That's archaic.

Q. So you think that the classification of the Bard product as lightweight, Type 1, monofilament, macroporous, polypropylene mesh is no longer true?

A. For 1997, when he came out with it, when Abed came out with that. I would look more at the Cobb study, which calls it heavyweight, 95 grams-per-perimeter-squared. And it calls the Prolift medium at 45 and Ultrapro Light at 28 grams-per-meter-squared.

Q. At the point in time when the Bard products were marketed and available on the market, were they considered lightweight for the time?

A. What component are you talking about, because they have a hybrid? They have thick arm meshes. The arms are thicker than the body. So Cobb's -- Cobb's article was in -- Cobb's article produced it in 2005. Avaulta came on the market in the end of 2007 or the beginning of '08. Polypropylene, 95 -- 95 grams-per-meter-squared; 45 was Prolene Soft, and Ultralight was 28, and they called that lightweight. So he calls it heavyweight.

Q. You're referring to Cobb?

A. Yes, I am, where he used the Bard product.

Q. And he calls it heavyweight?

Page 230

A. He calls it heavyweight.
Q. Anybody else call it heavyweight?
A. I don't know. Klosterhalfen. Actually, I shouldn't say I don't know. Yes, Klosterhalfen.
Q. Yes. Anybody else?
A. Probably Klingele. I would have to look at the articles on that one.
Q. I would bet you're right.
MR. CARTMELL: Klinge.
THE WITNESS: Klinge. Yeah, he's German.
VIDEO TECHNICIAN: Can we jump off real quick?
MS. GEIST: We need a break?
VIDEO TECHNICIAN: I need to switch my card.
MS. GEIST: Yeah. Sure. Let's take a break.
VIDEO TECHNICIAN: We're off the record. The time is 2:49 p.m.
(A recess was had.)
(Exit Mr. Brandon Morris.)
VIDEO TECHNICIAN: We're back on the record. The time is 3:03 p.m.
(Elliott Deposition Exhibit No. 11 was marked for identification.)
BY MS. GEIST:
Q. Doctor, let's continue our discussion, but I want to try and wrap it up shortly so we can move on.

Page 231

But let me mark, as Exhibit 11, another study by Nieminen and ask you if had looked and considered this one. Again, this is on the issue of dyspareunia. I hand that to you, or throw that to you. Thank you.
Again, Doctor, this study looked at women who had undergone a transvaginal mesh procedure to repair pelvic organ prolapse and women who had undergone a native tissue repair for their prolapse. Do you see that?
A. Yes.
Q. And, by the way, Doctor, this article notes that a posterior repair is associated with a higher risk and higher incidence of dyspareunia, generally speaking. Do you agree with that?
A. That is the -- that is correct.
Q. And that's what the literature tells us, right, not just this article? That's pretty well-established in the literature?
A. That is that posterior repairs can be associated with more pain following surgery.
Q. And in particular dyspareunia, right?
A. Or dyspareunia has been reported, yes.
Q. Okay. And the Nieminen 2008 study looks specifically at the incidence of dyspareunia in the mesh group versus the native tissue group, correct?

Page 232

A. Yeah. It's a randomized trial looking at those factors that you just mentioned.
Q. Right. And this study actually looked at the incidence rate at the two-year follow-up. So it's longer than the 12-month studies we looked at before?
A. No. They're -- no, that's not -- they're evaluated up to 12 months. So what I would have to do is look at the studies to find out how many made it two months -- 12 -- or, excuse me, 24 months. Because with that phrase there, that doesn't tell us how long they were studied. It's that some made it to 24 months. It would describe it in the results.
Q. Okay. And let's look at that in a minute. But the conclusions of this study are, as you see at the top, that the dyspareunia score was statistically significantly lower in the mesh group?
A. That is correct. That's what they report in this study with -- I'm trying to determine which product they were using. And, again, Nieminen tends to use Prolift.
Q. So just so I understand, Doctor, some of these studies that we've looked at I think you were critical about the time in which women were followed. It was too short for some of the studies, right?
A. There is no known study out there that is

Page 233

adequately valuing the risk of this product of the lifetime of a woman.
Q. Okay. So there is no -- well, strike that.
And this study, I assume you're going to tell me, well, it's sort of meaningless here because it didn't look at the Avaulta product in particular?
A. No, absolutely not. This is -- I mean, Kari Nieminen and then the other one, Heinonen, the senior author I've met. No. They've done good work here. This is a contribution to literature.
But what I'm saying is, if we're putting this in a 40- or a 50-year-old woman who has 40 or 50 years of life left in her, we don't know what happens. We do have animal data showing continued degradation as we've mentioned over and over. So at 24 months, that is good at 24 months, but what's going to happen on down the road?
Q. And you can't -- we don't have any study that tells us exactly that? It would be guesswork or it would be speculative to guess, right?
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. Well, I wouldn't say it's going to be speculative. I mean, in the animal model, up to 15 years we see degradation. And so there's no reason to

Page 234

think that degradation in humans, especially when it's contaminated or heavy -- heavyweight arms rolling, that this is going to continue.

Q. Well, looking at -- looking at actual women in this study, we know that there was a statistically significant lower rate of dyspareunia in the mesh group after two years, correct?

A. That is -- that is actually what they do report here. And, again, the mesh exposure rate of 8 percent I would want to know were these women -- you know, was that included into it or not. So -- but you stated it accurately. Based upon the findings and what these people found at 24 months in this specific study, which is a nonAvaulta study, the dyspareunia score was lower in the mesh group.

Q. There is no Avaulta-specific study that found a statistically significant difference in dyspareunia reports between the Avaulta mesh group and the native tissue group, true?

MR. CARTMELL: Object. Object to the form.

BY THE WITNESS:

A. Culligan, et al., Evaluation of Transvaginal Mesh Delivery System For the Correction of Pelvic Organ Prolapse; Subjective and Objective Findings At Least One Year. From what I understand, that is an Avaulta study.

Page 235

They had 11.7 percent extrusion and pain at 3.3 percent.

Q. I asked about dyspareunia, Doctor.

A. I would have to look at my studies here because I don't have them broken down. But they have Avaulta Plus Fractional -- Functional Results and Quality of Life, which that one you would think would have a discussion there of dyspareunia. So I have all of my studies, which are in my expert report. You should probably -- if you ask that question of which study has it, we need to go through it and find out.

But here is one. Bondili, B-O-N-D-I-L-I, et al, Two-Year Follow Up of Sexual Function Symptoms and Quality of Life After Innovative Procedure Avaulta Synthetic For Pelvic Organ Prolapse, that was presented at the ICS, International Continence Society in 2010. That study would have the data in there.

Q. Was there a comparison? Was there a nonmesh arm in that study?

A. We would have to get that study and look at it.

Q. Right. So that's what I'm trying to ask you. Do you have a study where there was a comparison between the -- a group of women implanted with the Avaulta product and a group of women who had prolapse repaired using a native tissue procedure?

Page 236

A. In a quick review of what I've got here, I don't see it. However, if -- in reviewing of the Bard depositions, I never saw anybody raise that, and that would be a very good one. I would like to see that if it exists.

Q. Okay. But that was my question to you originally. We're looking at dyspareunia rates between women experiencing native tissue repair and transvaginal mesh repair, correct?

A. That's what we've been looking at, yes.

Q. That's what we've been looking at. And, you know, some of your criticisms of these studies are, well, it's not -- it's not a specific Avaulta study. But there is no Avaulta study that has looked at the comparative rates of dyspareunia between an Avaulta arm and a native tissue arm in the study, correct?

A. I am unaware of any. And that seems to me to be a major fault of the product not doing that comparison. That's a very important study that should be done.

Q. The two Nieminen or Nieminen --

A. Mm-hmm.

Q. Am I saying that correctly -- studies that we've looked at, the 2008 and 2010 studies, those -- those both also looked at one of the quality of life

Page 237

issues we talked about before, which is the sensation of vaginal bulging?

A. Correct. They discussed it in their reports.

Q. Okay. Well, it was one of the -- they were looking at anatomic failure rates in those studies, right?

A. Yeah. They looked at anatomic and I believe -- we'd have to go through the studies in detail -- I believe they were looking at quality of life as well.

Q. Okay. So we just marked as Exhibit 11 the one Nieminen study, and we already marked as Exhibit 10 the other one. Do you have those in front of you, 10 and 11?

A. I have 11. I don't see 10. I would be able to look at 10 though. Okay.

Q. Okay. Well, my only questions for you for these two studies, Doctor, is they both looked at anatomic success rates and both studies concluded that transvaginal mesh had a better anatomic success rate or less recurrence of prolapse symptoms, correct?

A. I have to look at those. You're asking me to compare two different studies over different periods of times. I would -- I would bet -- how do I bet? I know these are comparing the same patients. This is actually

Page 238

one study that's extended out, I bet. So in these two studies were actually the same group of patients, the same group of patients. The findings you mentioned, that's what -- that's what their findings were on the non-Avaulta product.

Q. Well, I don't think that's right, Doctor. Because if you look at the one study, Exhibit 10, it's talking about 202 women in a randomized controlled trial who underwent either native tissue repair or a transvaginal mesh procedure. And then, if you look at Exhibit 11, the other study, that's talking about 97 patients in a randomized controlled trial?

A. No. 97 and 105.

MR. CARTMELL: Yeah.

THE WITNESS: So together that equals --

MR. CARTMELL: The same.

THE WITNESS: -- 200 and what?

MR. CARTMELL: 2.

THE WITNESS: 2, which is interestingly, on this other paper, 202. This is the same, these people.

BY MS. GEIST:

Q. No. You're right, Doctor. I'm sorry. That was my mistake.

A. Well, these people -- this was unethical, what they did. You have to acknowledge this is a

Page 239

continuation of a previous study. They are presenting this, and this is wrong and authors get caught up in this all of the time, and it's wrong, they are presenting this as two different study groups. Unless they state -- I would have to read this article very closely --

Q. Well, let's not do that.

A. No. You interrupted me.

Q. Oh, sorry.

MR. CARTMELL: Go ahead.

BY THE WITNESS:

A. Unless they state in here somewhere this is a continuation, they have done something that's unethical. They submitted it to, what journal here, International Urogyn and then they went over and submitted it to AJOG. Okay. Same authors. They're borderline unethical.

Q. Well, Doctor, I'm sure you don't want to make that statement until you read either paper cover to cover to make sure they didn't disclose what they did.

A. And what did they state? I'm sorry. I interrupted you.

Q. I don't want to get into the ethics of the authors. My only question to you --

A. Well, we should. We should. This is -- you're talking on record, and I'm stating on record, if

Page 240

they did not, they've done something unethical.

Q. That's fine, but that's sort of aside from the expert opinions you're offering in this litigation, right?

A. No. Because I'm an expert as far as dealing with, also, paper journal review, because I do it for a lot of them.

Q. I --

A. And you're presenting -- you presented two separate studies claiming that they're different. I'm saying they're not different, and so all of this should be stricken.

MR. CARTMELL: And you're cross-examining him with this.

MS. GEIST: Well, I'm --

MR. CARTMELL: I mean, he gets to point out the problems with the study. It's relevant.

BY MS. GEIST:

Q. The point is, Doctor, whether you want to say it's the same patient population or not, it doesn't matter to me. Because if it's the same population, they were followed longer than the original 2008 study?

A. Yes. But you present it as two separate studies with two separate sets of data that both support that the product is good. And I'm saying, no, that's

Page 241

not it. This is just the same continuation of people who have made questionable judgments.

Q. Okay. Well, you know what? That aside, and I'm not making any representations about these studies. I'm showing you different studies that were on your review list and mine. So any statements about same study or different study, I'm talking about two separate papers. I'm not trying to misstate or mislead anything.

But the point is, in both of these articles, and they may be the same patient population, in both of these articles, the authors concluded that they were better anatomical rates at the 12-month mark and then the three-year mark in the mesh group; is that correct?

A. Well, no. I'm not going to get beyond that these are the same patients. It's too much of a coincidence to have 202 patients in both of them. So I see one study here that's probably a continuation. And the findings that you recorded, that's what they state.

Q. Okay. So we'll just -- we'll ignore the earlier one. We'll just stick with the one that looked at women after three years and found that the recurrence rate of prolapse in the mesh group was only 13 percent compared to 41 percent in the native tissue group. That's what they found, correct?

A. That's what they state in this non-Avaulta

Page 242

study, yes.
Q. Okay. And -- and the mesh group did not have a higher incidence rate of dyspareunia after three years, correct?
A. According to what they state in this non-Avaulta study, that is correct. However, as I mentioned before, the mesh erosion rate was 19 percent. I bet those women were not sexually active during that time, and so this is actually somewhat false findings, misleading findings.
Q. And the other conclusion that the authors drew in this study was that the vaginal bulge symptom, which we talked about earlier, was statistically significantly lower in the mesh group. Do you see that in the 2010 paper?
A. Yeah. That is what they state in there. But, again, the worrisome fact of this is what's going to happen over time. If you look at Paper No. 1, exposure rate 8 percent. Paper No. 2, at three years, exposure rate was 19 percent. That is a progressive disease process. That is a defective product.
Q. Do you say that, Doctor, even knowing that some of the mesh exposures that were reported in this study do not require any treatment?
A. Yes, I do. That's a defective product.

Page 243

Q. So hold on a second. That's an interesting point. So if there is a mesh exposure, even though it doesn't require any type of treatment, any type of surgical intervention, if that happens, that means the product is defective?
A. Yes. It does. That's not a good product. That's a problem. Now, the severity of which, we can argue about that. But the native procedures do not have that. It's at zero percent.
Q. But ASCs do, do they not? There are mesh exposures associated with an ASC for any other implantation of mesh?
A. Yes. And the argument that's coming back on that is that 19 percent. The answer to that is, no.
Q. Well, hold on. You just said any mesh exposure means the product is defective?
MR. CARTMELL: Object to form. I think that misstates what he said. Do you mean mesh exposure?
MS. GEIST: No. I don't -- I don't think it does.
MR. CARTMELL: We were talking about 19 percent.
BY MS. GEIST:
Q. We just looked at a paper, five of the women who had mesh exposures didn't require any sort of surgical intervention, whatsoever?
A. Correct.

Page 244

Q. And your opinion to me just now is that the product is defective because there was exposure?
MR. CARTMELL: Object to form.
BY MS. GEIST:
Q. Is that your opinion?
A. My opinion is that we were seeing a progressive problem from 8 percent at one year to 19 percent. With this particular non-Avaulta product, we're seeing this problem. Sacrocolpopexies, yes, they can have extrusions rarely. As I mentioned, for the past 90 patients, zero.
Q. What's the incidence rate of mesh exposure for an ASC?
A. We'd have to pull out the data on that one.
Q. Okay. Let's do that, because I want to see what's your defining line of what makes a product defective or not defective based on the erosion rate.
Doctor, let me ask you to put the Carey study in front of you. Do you have that? We've previously marked that.
A. Yeah. I'll be able to find it. Carey, vaginal repair with mesh versus colporrhaphy.
Q. Yeah. In that study, Doctor, there was a mesh exposure rate of 5.6 percent in the mesh group, correct?
A. Well, this study is not comparing

Page 245

sacrocolpopexies.
Q. No. I know that.
A. They're --
Q. I'm just talking about -- I'm just talking about incidence of erosion rates using transvaginal mesh. The Carey study tells us and in that study there was 5.6 percent of the women in the mesh group who experienced erosion, correct?
A. I would have to see where you're talking about. I just don't -- because we're talking about sacrocolpopexy, and so I don't see a reference in here of mesh extrusion with sacrocolpopexies.
Q. No. And there is not. There is not. So let me restate it.
A. Oh.
Q. I want to show -- I want to talk about a couple of studies that looked at mesh erosion rates in the abdominal sacrocolpopexy.
A. All right.
Q. Okay. But in terms of what we see in the literature using transvaginal mesh, the Carey study tells us that there was 5.6 percent of the women in the mesh group had some mesh exposure?
A. At 12 months, which is very much similar to the other, the Nieminen study, we just reviewed. So the

Page 246

question would be what is it at at 36 months. Is it up to 18? I don't know. These patients weren't followed, but that's what it states.

Q. Okay. And then the -- in the Withagen study we looked at before, they also had an erosion rate in that study. There were 14 patients in the mesh group that had some degree of erosion. Do you see that in Withagen?

A. 16.9 percent at 12 months.

Q. And the erosion rates in that study actually varied significantly depending on what center the patient had the surgery at, correct?

A. I would have to look through that. And, actually, it was exposure rate, not erosion.

Q. Would you agree with me, Doctor, that sometimes, in the literature, exposure, erosion, extrusion are all used interchangeably?

A. Early on, but not currently. So I had to look when this was originally written in 2011. Because these complications are new and we didn't know how to necessarily manage them early on, we still don't necessarily know how to manage them. That remains to be seen. There is confusion in the literature, but I'm saying currently -- and they say exposure. That's why I'm just making sure we're clear it's not erosion,

Page 247

because that's obviously a different beast.

Q. In the Withagen study, though, they note that some of the centers that performed the surgery had a 0 percent erosion or exposure rate, actually exposure rate, and some of the centers had a greater rate, even 100 percent. Do you see that?

A. I don't -- I don't see it. I have heard it elsewhere.

Q. Okay. Would that indicate to you, Doctor, that the risk of exposure or erosion depends in a large degree on the skill and technique used by the surgeon?

A. Well, that reflects in this study they had that finding. But if you go to the other ones, you know, the Carey, you know, this one is in Australia, which is a large volume center. The other ones they didn't report that. So all I can do is, based on your question, in this one study, that is what they found. The question is, was it statistically significant or just by chance.

Q. Okay.

A. And so it was underpowered, so I'm sure they wouldn't -- they wouldn't be able to do that.

Q. But in terms of trying to compare the incidence rates between the ASC and transvaginal mesh, we know from Carey it's 5.6 percent. It was 5 percent

Page 248

in Nieminen's -- Nieminen's 2010 study?

A. Well, again, those studies, at 12 months, it's what you -- what you reported there.

MS. GEIST: And, sorry, the videographer is trying to tell us something. What's wrong?

VIDEO TECHNICIAN: (Inaudible.)

BY MS. GEIST:

Q. Okay. Did you look at the Nygaard 2004 study?

A. I recognize the name.

Q. Okay. Let's take a look at that one. That specifically looked at the erosion rate for mesh being implanted using the abdominal approach, the ASC approach, right?

A. Yeah. This is the Kari study, yes.

Q. Okay. So, in this study, we see a similar erosion rate of 3.4 percent; is that correct?

A. I agree with you. Well, I don't see where they say 3.4. I can't say that that is a similar rate, but that's what they report in here.

Q. 3 -- I'm sorry. Go ahead.

A. In these other studies, and this is what's important, is we'd have to look at the absolute numbers. In the Kari study with Nygaard -- Nygaard, Brubaker, you know, and Geoff Cundiff -- and I know a lot of these people here -- that's 215 of one specific study or one

Page 249

specific type of surgery.

These other ones are going to be randomized, so they have smaller numbers in their arms. So in 93 patients, in the Withagen paper, so, you know, half, less than half was short follow-up, they had a higher rate. So, again, you can't compare. It's not apples to apples. You can't do that.

Q. Well, let me show you what I've marked as Exhibit 12, which is the Nygaard study we just started talking about.

(Elliott Deposition Exhibit No. 12 was marked for identification.)

BY THE WITNESS:

A. Yeah.

Q. Do you have it?

A. I have it here.

Q. All right. I'm just going to put it down there for our pile anyway.

A. And I'm seeing what we have as far as --

MR. CARTMELL: We have a pile.

MS. GEIST: You have a pile, too?

MR. CARTMELL: Yeah.

BY MS. GEIST:

Q. All right. I'm getting the overall rate of

Page 250

mesh erosion at 3.4 percent from the section of the study on the left-hand side entitled, Tabulation, Integration, and Results?

A. Yes. And in that -- yes, you are quoting that correctly, I believe. I still don't see the mesh erosion in there. But, important to note, this is five- and seven-year follow-up. We now have with Withagen or Nieminen, we have one-year follow-up at 8 percent; three years, 18-point something percent. Wasn't it? Or whatever. I don't -- I don't remember exactly what the number was.

MR. CARTMELL: 19.

BY THE WITNESS:

A. 19 percent, and this is five to seven years with 3 percent. That is significant. Because we cannot compare the Kari study with the other ones until the other one gets to five to seven years.

Q. So the Nieminen -- the Nieminen or Nieminen 2010 study looked at the erosion rate at the three-year period, and that was 5 percent. Do you see that?

A. I'm trying to find it. I've got papers everywhere. Nieminen, I have one of them here.

Q. The 2010 one is the one I'm referring to, Doctor?

A. Okay. Yeah. I'd have to pull that study back

Page 251

up here. That's a difficult name to spell, Outcomes after anterior vaginal, here we are.

Q. I keep saying Nieminen, but maybe it's Nieminen?

A. I've heard Kari speak, and I don't know how she pronounces her last name. At three years, it was 19 percent. The same study at one year was 8 percent. So until they get out to five to seven years, we can't compare those two studies. And, if anything, this makes -- makes abdominal sacrocolpopexy look very, very good.

Q. How about the Wu study from 2006? Did you look at that one?

A. I do not recall that name.

Q. Let me see if I have a copy of that. That's another study looking at erosion rate using the abdominal sacrocolpopexy.

A. And with that said, that was perfectly acceptable. I'll really look forward to seeing it because I'm interested in this subject. But the Nygaard paper, the Kari study, is arguably the best, better than my studies, of looking at large volumes with multicenter and their results. So it would be interesting to compare a smaller study.

Q. So I have to look at your reliance list and

Page 252

see if you looked at the Wu 2006 study. That had a 5.4 percent rate of mesh erosion for ASC procedures. I don't have a copy with me. I don't know if you have it.

A. I don't -- do you know how to pronounce the last name?

Q. No. It's, W-U?

A. W-U, no. I do not have that one.

Q. But I guess my question to you, Doctor, is, when we look at 5.4 percent or 3.4 percent and some of the other studies we looked at were 5 percent for transvaginal mesh, your criticism of those studies is that they didn't look at the erosion rates long enough?

A. Absolutely. Because, again, look at the sacrocolpopexy, the Kari study. It's been a while since I've looked at this one. Five- to seven-year follow-up. That is incredible. Median follow-up, seven years. And if we're seeing a curved increase from one year at 8 percent, three years at 19 percent, that's a curve that's going up. So what is it going to be at seven years? I don't know.

Q. Well, it would be speculation to say whether it would be any higher, wouldn't it?

A. The erosion -- the extrusion rate will not go down. Once a patient had exposure, you can't eliminate them from that. So it's only going to go up. That's

Page 253

basic statistics.

Q. If new -- if new patients experience exposure or erosion?

A. Or if a patient has been treated and she has a repeat exposure.

Q. Let me -- let me flip for a second and show you what I'll mark as Exhibit 13.

(Elliott Deposition Exhibit No. 13 was marked for identification.)

BY MS. GEIST:

Q. Doctor, and for the record what I've marked as Exhibit 13 is an article entitled, Time to Rethink an Evidence-Based Response From Pelvic Surgeons to the FDA Safety Communication: Update on Serious Complications Associated With Transvaginal Placement of Surgical Mesh For Pelvic Organ Prolapse?

A. Correct.

Q. I hope I read that correctly.

A. No. I'm familiar with this paper.

Q. Okay.

A. And I'm familiar with one, two, three, four, five of the authors.

Q. Okay. These are all well-known reputable pelvic floor surgeons specializing in women suffering from pelvic organ prolapse; is that fair to say?

Page 254

A. They're well-known.
Q. Are some of them reputable, some of them are not?
A. No. I'm saying that these are well -- some of these are very, very well-known to be making seven figures a year from industry, and that is a concern for me.
Q. Who is making seven figures a year from industry on this paper?
A. Lucente.
Q. Anybody else?
A. Murphy, possibly. I don't know how much --
Q. So you don't know?
A. I said some of them and Lucente would count as some. Murphy, I don't know how much he makes. I don't know how much Goldman makes.
Q. You make money from the plaintiffs' bar, do you not, Doctor?
MR. CARTMELL: Object to form.
BY MS. GEIST:
Q. Well, do you make money, a third of your income over the last three or four years, from the plaintiffs' bar?
A. I make money -- you are correct. I do make money, but it's in the fight to protect women that I

Page 255

have to deal with all -- every day. I do not make money in implantation of a defective device that ruins some women.
Q. But that's your opinion, is it not, Doctor?
A. It is my opinion based upon fact.
Q. Well, before we looked at the AUGS position statement, and that position statement, as we discussed together, talks about the importance of allowing synthetic mesh materials to be accessible to women who need those materials to repair their pelvic organ prolapse. And there are physicians who believe in continuing to permit and allow that option to be available for women. Do you disagree with that?
A. Well, we've gone over this already. And I'd have to state that, when a doctor, whoever he is, or any study that is industry-sponsored, there is an increased risk for there to be a bias introduced and favorable of that company, and those are all referenced in my bibliography, which I can't find a copy of right now.
Q. Well, there is a risk of bias in any study, correct?
A. Yes. But when money is involved, there is a reason why they have a phrase follow the money.
Q. Well, so if there's money involved or paid to you, there is a risk of bias in things that you say as

Page 256

well; isn't that fair?
A. No. I think that's a mischaracterization.
Q. Well, how is it different for you?
A. Because my opinion -- I'm sorry. Go ahead.
Q. No. But how is it different -- how is it different from you? You made a very strong statement against some very reputable, skilled surgeons who treat women suffering from pelvic organ prolapse about -- and, you know, you essentially implied that their -- their opinions are biased because they're paid by industry.
How is it that you and other experts who are compensated by the plaintiffs' bar are not similarly biased?
A. My opinions were established prior to this lawsuit, any of this litigation. Okay. I made comments with Public Citizens, Ralph Nader's group, about this prior to all of this. I was -- so I am not involved. I don't make a dime off of inserting something into a woman or not. I am trying to protect women that I see on a daily basis. That is different than writing a paper, studies, those types of things.
Q. Do you think these doctors are not acting in the best interest of their patients?
A. I can't answer as to all of them. I mean, I know Howard Goldman is very, very good doctor. I

Page 257

respect him immensely. We have kindly debated this subject as of last year in May, okay. We talked about it at the SUFU meeting within the AUA. He's a very good person.
The other ones, Murphy, Lucente, and van Raalte -- well, Kohli I also kind of know. I haven't talked to them. I don't know. But I'm not saying they're not good surgeons. Be very clear about that. They could be a very, very good surgeon. But when I see somebody who makes a lot of money and comes out in a statement that is in support of them making a lot of money, so be it. When all of this litigation stops, I go back to taking care of patients on a daily basis. Okay. So I see the possibility of bias.
Q. So you discount the positions taken by these surgeons on behalf of the Pelvic Surgeons Network because you think they're all biased?
A. The Pelvic Surgeons Network is a made-up group. That's not an organization. That came about -- you have to look at the politics of that. That came about with all of this mesh litigation. They got together, everybody who puts in mesh, and said, Ooh, let's band together and make a statement.
So that's not a preexisting that's been around for five, ten years that has fought through this. No.

Page 258

Those are all people who -- and if you go down the list, I can't give you a specific number -- how many make money from industry. And that's a dangerous process. That's why manuscripts, everything, now have to do a full disclosure of how much money you make where.

Q. So the 600 surgeons who take care of women suffering from pelvic organ prolapse that signed on to the response to the FDA safety communication, do you think they're all biased, too, and motivated by money they make from industry?

A. I would never say all. I say there is the potential. And what would be very interesting, this statistic is available, how many make money from companies. And that is not disclosed on there, how many make money.

Q. The AUGS statement that we referred to and discussed earlier together, do you have that in front of you yet?

A. Sorry. I thought we were done with it, so I tossed it. Here. I have that now, yes.

Q. Okay. Do you see on page 2, at the top, this is where we had stopped reading, page 2 at the top?

A. Yes. I'm there.

Q. If you go down to the fifth line of that paragraph --

Page 259

A. The top paragraph?

Q. Actually, you know what? Let's start on the third line. I forgot to ask you about this. On the third line of this paragraph, in the AUGS position statement, it says, A ban on the use of synthetic mesh materials would potentially prohibit many women from accessing the full range of treatment options available. Is that something you would like to see?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. I would have to read the whole document, because I don't know if they're talking about just POP or the slings because you're talking about a mixed bag here. According to this, effectiveness of POP mesh.

Q. This is talking about POP mesh.

A. Okay. If we are under the understanding that this is specifically POP mesh, so everything I'm going to state from this point on about this document is going to be on POP mesh, then I agree with that statement. Oh, excuse me. Excuse me.

Q. You would with the ban --

A. I agree with the ban, that's correct.

Q. All right.

A. Let me be very clear. I'll start over. I agree that a ban is the appropriate thing, but not an across-the-board ban. I'm saying that, perhaps, in controlled circumstances, with controlled surgeons, with very unique situations, fully informed patients, randomized controlled trial, non-industry supported, then they could possibly, in those individuals, do some work. Okay. A full ban on just random use for everybody to put in any women, I do agree with that. Does that make sense?

Page 260

Q. No.

A. No one, okay.

Q. So -- no.

A. Do you want me to start over?

Q. No.

A. Okay.

Q. I'm trying to understand because, back in 2011, you joined in the petition to the FDA for a complete and full ban of all pelvic organ prolapse mesh products, correct?

A. Until further data is available and non-industry supported to support that it has some benefit.

Q. But unless -- at the time, if there was an absence of that data, you were looking for a ban on the products at the time. So it wouldn't be available to this small percentage of women in the population that you just described?

Page 261

A. No. I -- I am of the position. We have to be very clear about this. I stated it in the record already. The routine use of POP transvaginal mesh should be banned until there is further data available long term to say it's safe in women and that the benefits outweigh the risks. Right now there is not any data of that. You know, the FDA came back with that 522 to all of the companies, as far as I know, Ethicon, Bard, and they were not able to produce data that met the FDA requirements for that 522.

So that data is not available. I am definitely clearly against, based upon my experience from day-to-day dealing with patients, the international clinic, et cetera, et cetera, that routine use should be banned.

Q. Do you agree with the statement in the AUGS paper that there are certain clinical situations where the use of transvaginal mesh would be preferred?

A. Like I stated before, remember, I had all of those multiple different criteria.

Q. Right.

A. I probably won't remember all of them.

Q. Right.

MR. CARTMELL: Haven't we talked about that in

Page 262

depth?
BY THE WITNESS:
A. I -- I can go over it again. I don't mind. In highly advanced surgeons with a woman -- and, again, I'm not going to have all of the data, so we have to go back to my previous statements. A woman fully informed, in certain unique circumstances, it might possibly be acceptable. However, in my experience at one of the largest -- the largest institution in the United States, we have not needed -- we have never come to that.
Q. Let me -- let me go back to the Time to Rethink article that I put in front of you, Doctor. The authors indicate that they performed a systematic review of the scientific literature from 1996 to 2011, similar to what FDA did; do you see that?
A. Yeah. That is -- that is what they stated.
Q. Any reason to believe they didn't do that?
A. Well, I have no reason to support it or not. I looked at the bibliography, and it's 25 articles. There are hundreds and hundreds. I mean, I have 509 in mine. So they only have 25. So I can't state they did it. I have no reason to think they did not.
Q. Would you -- let me see where you agree and disagree with some of the statements in this Time to Rethink article. Okay?

Page 263

A. Okay.
Q. If you go to -- it's actually page 6, for whatever reason, of the article. It's actually the second page, but on the top it says 6?
A. That's because --
Q. Do you see that?
A. Yes. That's because this is an editorial piece. This is not peer reviewed, and so it's right at the very beginning, which is important to note. So this has been -- again, it's an opinion piece.
Q. It is an opinion piece. No one is stating otherwise. It's supported by 600 surgeons who take care of women with pelvic organ prolapse, true? I mean, 600 surgeons in the United States signed off on this?
A. In 2011, I'll take your word for it as far as 600 surgeons put on there, but I also said the caveat of how many were getting paid by industry.
Q. Well, you don't have to take my word for it. It says, on the first page of the article, that the manuscript has been endorsed by over 600 members of the Pelvic Surgeons Network, and a list of those surgeons are included with the article?
A. Yeah.
Q. Hopefully, in the copy I gave you.
A. I don't -- that's fine. I don't need it.

Page 264

Q. Okay. Are you dismissing -- I just want to understand. Are you dismissing the conclusions reached by the authors here and the 600 surgeons who endorsed it because you think they're all biased in favor of industry?
A. No, absolutely not. That's minimizing what I said and my experience. Two things, it's 600 surgeons out of how many? Number two, you're just taking the pelvic -- pelvic whatever network, which is a recently made-up thing. And so based upon what you're saying, yes, that is what this non-peer-reviewed article stated.
Q. Now, I assume you agree with the statement that there is no question that mesh placed abdominally in the form of an abdominal sacrocolpopexy is an excellent procedure for treating POP?
A. In certain patients, it is, yes.
Q. And would you also agree that surgical technique appears to play a significant role in the rate of mesh erosion and the rate varies greatly between the studies?
A. Some of the surgeons that I respect the most, the TBN group out of France, arguably the highest volume surgeons, they are reporting -- they are reporting extrusion rates 15 to 20 percent. So I agree that there is going to be variations in the exposure rate, but some

Page 265

of that could be due to the duration of the study. The surgeon's role plays a role. The surgeon's training does play some role. I cannot say how much of a role.
Q. The study looked -- well, strike that.
This paper looks specifically at the incidence rate of erosion comparing transvaginal mesh to the ASC procedure. Do you see that?
A. I'd have to -- page 2, I believe you're on?
Q. Page 3, actually.
A. Page 3. Okay. So which is page 7?
Q. Right.
A. Okay.
Q. It's a little confusing.
A. Oh, here we are, erosion.
Q. Do you see under, Erosion? Do you see the author knows --
A. Yes.
Q. -- that the results, at least in two large, multicenter trials, the results of the abdominal and vaginal approach are quite similar in terms of erosion rates?
A. Yes. But they're -- you know, they're cherry picking. Let me see what study they're quoting here, Study No. 20, Brubaker, Nygaard -- well, see, they're not even quoting the Kari study, which is the biggest

Page 266

one out there. So, yeah, the studies that they have quoted, I will not argue with the data they have written down here.

Q. Would you agree, at least, Doctor that, while they're choosing to discuss certain studies, you're discussing certain studies, we've looked at other studies, there is varied rates of erosion in all of these studies with respect to transvaginal mesh and the ASC?

A. There are varying numbers of extrusion rates out there. The ramifications and the frequency and the severity and the complications are going to be different, which are not discussed here. But I'll agree with you, there's varying rates out there.

Q. And I think we've -- I think we've beat this like a -- like a horse, but I think, on the next page, you would agree with me and agree with the statement that mesh erosion is a risk any time mesh is used in reconstructive pelvic surgery and that surgical experience and technique play a significant role in the risk of erosion?

A. Yeah. We've beaten this thing. I disagree with that.

Q. Okay. I just wanted to make sure.

A. For the aforementioned reasons that even, in

Page 267

high-volume, very talented surgeons, they're having an unacceptably high extrusion rate.

Q. Let me show you quickly, Doctor, your -- I think I'm on Exhibit 14. Okay. We're all in agreement on some things, right?

MR. CARTMELL: Mm-hmm.

(Elliott Deposition Exhibit No. 14 was marked for identification.)

BY MS. GEIST:

Q. Let me show you Exhibit 14, Doctor, which is a copy of the FDA petition that we talked about before. And this was the petition to the FDA by Public Citizen back in August -- August of 2011?

A. Correct.

Q. I assume you reviewed that and signed off on it?

A. Yes.

Q. You actually are a signatory to the petition; is that correct?

A. That is correct.

Q. And you, along with Public Citizen, were seeking government involvement and an actual, I guess, order from the government to order all manufacturers to recall their products?

A. Well, that's an oversimplification of this. I

Page 268

mean, it's a lot of data to support that opinion.

Q. Well, I don't mean to oversimplify. But let me point you to the request.

A. And I can just cut to the chase. Yes, you're right.

Q. Well, hold on. All right. Okay. Because on the first page it says, what you're asking is to ban the marketing of all currently available, nonabsorbable, surgical mesh products specifically designed to treat POP. So you're asking for a ban of the marketing of all products, correct?

A. That's what the document states, yes.

Q. And -- well, that's what you wanted, right?

A. Yeah.

Q. And the second part, the second request to FDA, is an order that all manufacturers of nonabsorbable -- nonabsorbable surgical mesh products designed for POP, to recall the products. So you wanted a recall order immediately of all products?

A. That's what it states, yes.

Q. Then there is no caveats in here about, Well, let's wait and see. Let's look at studies. This was requesting an immediate recall at that moment, urgent request, pull all products from the market. That's what this was asking for, right?

Page 269

A. Correct. Based upon that on a daily basis I see these individuals, and I have seen individuals who have been implanted after this document. So when we wrote this up with Michael Karram, who is -- who is the, Carome, excuse me, who is the deputy officer involved with this. He is the one who wrote the document. I completely signed off on it. My opinion was -- is that extremism in the protection of women and their bodies was justified in this situation. Because if one more woman is permanently injured by a product that has no benefit or minimal benefit, that is unacceptable.

Q. Did you know Dr. Carome before you participated in this FDA petition?

A. No. He e-mailed me out of the blue.

Q. How did he find you and why, do you know?

A. I have no idea. I got an e-mail from him, from Public Citizen, or he went through our media department. I don't know. I don't recall how that actually happened. He contacted me. I did not want to get involved at all. I told him I did not want to get involved. I had enough headaches.

And he is the one who convinced me stating that he asked me a lot of questions, you know, are you seeing these type of people? And, I said, yes. He says, you have a moral obligation to be helping out

Page 270

these women, and that's why I signed on.
(Exit Mr. Jeffrey Kuntz.)
BY MS. GEIST:
Q. Do you know who funds the efforts of Public Citizen?
A. No. People. Industry.
Q. Industry?
A. No.
(Enter Mr. Jeffrey Kuntz.)
BY THE WITNESS:
A. No, you're right. Not --
Q. You're saying medical device companies --
A. No, not medical device.
Q. -- funds Public Citizen, do you?
A. As far as -- no. As far as I don't know who all gets involved in the funding of it. I know there's been -- they deal with it. I don't know where the money comes from; but, no, not medical industry.
Q. Do you know whether the plaintiffs' bar funds Public Citizen?
A. I have no -- I'll be on the record very, very clear. I have no idea where one single dollar comes from to fund them. I don't know.
Q. Wouldn't you want to know maybe something about the motivation of an organization like Public

Page 271

Citizen? We've been talking a lot about why people are putting articles out there and what motivates them.
A. Sure. No.
Q. Wouldn't you want to know what motivates Public Citizen?
A. You raise a very good point. I did as much looking into it. I never did come out and ask that specific question. But that's a good one. I can give Michael a call or an e-mail.
When I looked into where the money is coming from, all I could find is that, when Ralph Nader ran for president, he was no longer going to be in charge of Public Citizen because they thought it introduced bias, which I respected that position. But, no, I do not know where money came from.
Q. Would it surprise you to learn that certain members of the plaintiffs' bar fund Public Citizen?
A. I'm not -- after getting involved in this whole mesh issue, I'm not surprised at much anymore. Individuals I respected have changed their writing styles based upon funding, which has come out in trial, like Altman in the Gross trial versus Ethicon.
If lawyers are supporting this, I'm not necessarily against it because I have made public statements that, unfortunately, to the denigration -- I

Page 272

don't know if that's the right word -- of my own profession. Lawyers have led the way in getting this problem solved.
Q. I noticed that, in one of your articles, you made that statement after you had already received quite a bit of compensation from the plaintiffs' bar, true?
A. No. I disagree with that. I wrote that article in September of '11. Chris Winters, who is the chair of SUFU, asked me to write it for Current Opinions of Urology. At that point in time, maybe a month or two -- I would have to look at the specific dates. So, as far as a significant amount of money, I don't know what I had made, but it was not a -- I probably couldn't buy a car with it.
Q. Well, you all -- let's not get into the details of how much you were being paid by the plaintiffs' bar at the time. But you were being compensated by the plaintiffs' bar at the time you wrote that article and talked about how wonderful it was that lawyers are leading the charge --
A. No.
MR. CARTMELL: Wait. Hold on.
BY MS. GEIST:
Q. -- in the pelvic mesh litigation; isn't that true?

Page 273

MR. CARTMELL: Object to the form. You keep saying that they're being paid by the plaintiffs' bar. He's never been paid by the plaintiffs' bar. He has been retained as an expert in litigation by certain attorneys. And your continual statements of payments by a bar on the plaintiffs' side in inappropriate. It's argumentative and it misstates facts.
BY MS. GEIST:
Q. Okay. Well, you're paid by plaintiffs' counsel or plaintiffs' lawyers in this litigation and in the Ethicon litigation; is that accurate?
A. Correct.
Q. And when you wrote this article, Doctor, which I'll mark as Exhibit 15 -- I hope that's right. And I'm not getting any better at using the stamp as we go along today.
MR. CARTMELL: Thank you.
MS. GEIST: You're welcome.
(Elliott Deposition Exhibit No. 15 was marked for identification.)
BY MS. GEIST:
Q. Do you have Exhibit 15 in front of you, Doctor?
A. Yes, I do.
Q. Okay. When -- when you wrote that article,

Page 274

that was published in 2012, correct?
A. July of 2012 it was published.
Q. And, at that point in time, you had already been retained as an expert for certain plaintiffs by plaintiffs' lawyers in the pelvic mesh litigation, true?
A. Correct.
Q. And, on page 280 of the article, which is, again, sort of misleading, right, because it's six pages?
A. Correct.
Q. For some reason on the bottom left it says 280?
A. That just because Current Opinions of Urology continues January 1st with page 1 and then December just continues right on through, so that's why.
Q. Okay. And, in this article, under the discussion, this is where you essentially applaud the plaintiffs' lawyers for doing something about the pelvic mesh problem as you call it, correct?
A. No. I do not applaud them. I say sadly, for whatever reason, it seems to be them, meaning lawyers, not us, doctors, looking at the data, recognizing something is wrong, and aggressively trying to stop mesh use. This is a condemnation of my -- myself and my peers. This is not praising lawyers. That's the last

Page 275

thing I'd ever want to do is praise a lawyer. We're told that from day one. This is a condemnation of my own profession, and this is something I have stated in audiences. This is -- this is not a new thought.
Q. Okay. And all of that withstanding, at this point in time, you had already been providing expert opinions against manufacturers when you published this for more than a year, right?
A. No. That's not correct at all. September of '11 is when Mr. Anderson first contacted me, or right around there, very, very close. That was my first interaction. I was asked, perhaps, in October, we had a visiting professor, Dr. Christopher Winters, the chair of SUFU, a very powerful position, he knew my position on meshes. He asked me to write this opinion piece. Again, it was in October. I wrote the piece. It just took seven months for it to come out.
Q. So how did you know that the legal community, as you write under the discussion section, you write, It seems the legal community is significantly ahead of the medical community in realizing the magnitude of the problem and doing something about it?
A. Because that's a true statement.
Q. Well, how did you know?
A. Because I am in the medical community, I am

Page 276

attending the meetings, we are hearing of the complications, and no physician that I knew of, including myself, had really done anything to try and stop it.
Q. Well, how did you know the legal community were involved in the issue at this point in time --
A. Well.
Q. -- if you hadn't yet been talking to the lawyers about it?
A. No. You know, at this point in time, the FDA had already come out with their warnings and things like that, and you can't turn on a TV without hearing about all of these lawsuits.
Q. So do you think this paper is the reason why you got retained by counsel?
A. No, absolutely not. This was -- this was written after they had contacted me. But in February of 2011, at our national meeting, I presented an article -- or, excuse me, I gave a talk and talked with all of the -- you know, I just did a Google search and came up with all of the various different lawyers searching for cases. So that was well-known that was going on. I -- this, again, is a condemnation of me and my colleagues of not doing something to protect women. Okay.
Q. So this was written after you had been

Page 277

contacted by plaintiff's lawyers?
A. As I mentioned, in September or so of 2011, Mr. Anderson had contacted me.
Q. Did -- are you working with Citizens Petition -- I'm sorry. Strike that.
Are you working with Public Citizen on any other types of petitions to ban any other types of products or any other activity?
A. No. Every once in a while Michael Carome, again, who his title is -- whatever his title is here, he is the one in charge of things, will contact me when some issue is coming up for the FDA. It's been a long time, a year or more on that. Deputy Director of Health Research Group, Michael Carome, again, he is responsible for getting me involved in stuff.
Q. Does Mr. Carome --
A. Dr. Carome.
Q. I'm sorry. Does Dr. Carome or anybody else at Public Citizen compensate you for your consulting work with that group?
A. No. If anything, it is adding work onto my schedule without any compensation, but I'm doing that to help.
Q. You do it for free?
A. I do it for free.

Q. FDA, of course, denied the relief that you and Public Citizen were seeking, right?
MR. CARTMELL: Object to the form.
BY MS. GEIST:
Q. Well, you wanted -- you wanted an immediate and urgent order to pull all products from the market, and the FDA disagreed with you, correct?
A. The FDA made a decision not to the extent that I felt was appropriate.
Q. They disagreed with what you wanted?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. No. I didn't say that. I said they didn't go to the extent that I wanted them to go.
Q. Right. You wanted them to immediately pull all products from the market, and they didn't? They wouldn't do that, correct?
A. Yes. And if you look at the people who are on that FDA board, I don't believe a single one of those is the one who is taking care of these mesh complications. That's besides the point. But at least we have -- the fact that it failed to get to the extent that I wanted is not an issue for me. It's we're trying to make a difference in these women's lives.
Q. And you wrote separately, in support of that

position -- I'm sorry. Strike that.
You wrote separately, in support of the request, to remove and immediately ban all products from the market?
A. There was a follow-up something. I don't recall the details on that one.
Q. All right. Let me --
A. But I would have to look at that document. But, yeah, there was a follow-up petition.
(Elliott Deposition Exhibit No. 16 was marked for identification.)
BY MS. GEIST:
Q. Okay. Well, let me show you what I've marked as Exhibit 16. This is a separate letter from you, Dr. Elliott, to the FDA in strong support of the Public Citizen petition, correct?
A. Yes, which is very, very, very important. The date on that is prior to me having any interaction with any legal team. Okay, August 19th, 2011.
Q. And if you look with me down at the last paragraph, the fourth paragraph in your lower, sort of in the middle --
A. The fourth paragraph, the bottom?
Q. Yeah.
A. The last? Yes, I'm there.

Q. The fourth paragraph, are you with me?
A. Yes, I am.
Q. And on the fifth line, you state in your letter, I do feel this position is extreme. Do you see that?
A. Mm-hmm. Yep. I see it.
Q. So, at this point in time, your position and your opinions and thinking in 2011, you admit was extreme?
MR. CARTMELL: Well, objection. That misstates it.
THE WITNESS: Yeah.
MR. CARTMELL: And you add a bunch of additional things. It says what it says, and your question is misstating what the letter says.
THE WITNESS: Yeah. That is -- I'm sorry.
BY MS. GEIST:
Q. Does the letter say --
MR. CARTMELL: Why don't you read it?
BY MS. GEIST:
Q. And it stands on its own. It says, I do feel this position is extreme?
A. Absolutely. It states it. And as it continues, However, extremism in the pursuit of surgical responsibility, patient care, financial responsibility, and medical ethics is the only honorable end point. So,

yes, and I stand by that then and I stand by it now. If anything, it's more firm of a conclusion.
Q. And that's -- that's fine, Doctor. But I asked you earlier back in 2011 if you thought your position was extreme. Back in 2011 we had a group of pelvic floor reconstructive surgeons writing in response to the FDA petition setting forth their statements that women needed to have transvaginal mesh as an option. We had 600 surgeons sign on to that document. And in contrast, you were working with Public Citizen to get an order immediately banning and recalling all products?
MR. CARTMELL: Okay.
BY MS. GEIST:
Q. Isn't that position extreme at the time you made it?
MR. CARTMELL: Okay. Object and move to strike the statement of counsel. I'll also note for the record that your statement that you asked him previously in this deposition, if his position was extreme, related to the FDA actions he wanted. You had never asked him that previously in the deposition. So that was a misstatement of what you asked.
BY MS. GEIST:
Q. Well, the record is what it is. But can you answer my question, Doctor?

A. Absolutely, and I can answer that very clearly. 2011 is 365 days. As of August 19th, I make that statement. Prior to that time, a month or two prior, is when Mr. -- or Dr. Carome contacts me and I start looking at the literature and what he had written up. Okay. And so my position evolved. So, in 2011, I can still make a comment that I was not extreme. But, again, extremism in taking care of patients and women and their bodies is not a wrong thing. And I'll stand by that and I'll state that over and over and over. And I'm proud of that.

Q. So notwithstanding what you're saying in your letter to a government agency, you're telling me you don't think you were extreme back then?

A. You have to look at the entire document, not just one. If all I wrote on here, To whom it may concern. I do feel this position is extreme, period, and signed it, that's a foolish statement. I put qualifiers. I say why and I follow it up saying extremism, in this situation, responsibility, patient care, financial, medical ethics is the honorable thing. That's a good thing, and I'll stand by that.

Q. Doctor, let me show you -- I think I'm up to 17.

(Elliott Deposition Exhibit No. 17 was marked for identification.)

BY MS. GEIST:

Q. Doctor, let me show you what I've marked as Exhibit 17 to your deposition. And, for the record, this is a copy of an article that was on the Levin Papantonio Website. Do you see that?

A. Yes, I do.

Q. And this was published on the Website back on August 19th, 2011?

A. I'll trust you on that. I don't know. I don't see a published date.

Q. If you look under the title, it says, Mayo Clinic Doctor: Mesh patients have suffered needlessly. And underneath that, it says --

A. Yes.

Q. -- August 19th, 2011. Do you see that?

A. Yes, I do.

Q. Do you know who Levin Papantonio are?

A. I don't recognize those names, no.

Q. They're a plaintiffs' law firm involved in the mesh litigation. Were you working with them back in August of 2011?

A. No. I have no idea who they are. If you search my name and mesh and Publish Citizen, there will

be about a thousand hits on it. It's been taken. And I don't necessarily appreciate lawyers using it in that fashion, but I have no control over that.

Q. Okay. Well, that was my question. Were you aware of this? Were you being compensated --

A. No.

Q. -- by Levin Papantonio to use your statements on their Website?

A. Absolutely -- I have not received a dollar from anybody as far as posting comments, and we get those things frequently.

Q. How about the Mesh News Desk?

A. No.

Q. Do you remember being interviewed by somebody from the Mesh News Desk?

A. Yes. Julie Akre or something like that.

Q. Do you know who runs the Mesh News Desk?

A. No, I don't. I know they have solicited money from me to support putting my words on her page, which I didn't like.

Q. Have they ever provided you with any compensation for your statements that they put on the Mesh News Desk site?

A. Zero. And recently, as of, I don't know, a month or two ago, she contacted me asking for money to

support her Web page, and I say, no. So that Website I am not a supporter of.

(Elliott Deposition Exhibit No. 18 was marked for identification.)

BY MS. GEIST:

Q. Let me show you Exhibit 18, Doctor. This is the -- this is a copy of one of the articles on the Mesh News Desk site. This appears to be pretty recent, from October 27th, 2014?

A. Yeah. It's one that was posted, yes.

Q. And that's you. That's your smiling face there on the article, right?

A. Yeah. It's an updated photo.

Q. I'm sorry?

A. It's an updated photo. I don't know where she got it. That's interesting. She must have got it off the Web page, Mayo's Web page.

Q. But you provided her with the interview that's set forth here, correct?

A. She interviewed me, took lots of notes, sent me a manuscript that was severely false. I then edited it to what it is, and I have not reviewed this final one because it got posted without my permission. So, again, I am not a supporter of the Medical Desk.

Q. But, at least, you know, some of the

Page 286

statements in here, Doctor, seem to be consistent with our discussion here today. If you look at page 2, there is a question, Should it be off the market, referring to transvaginal mesh?

A. Yeah. If this is quoting me correctly, and I have been consistent with what I've stated. But I'll say it should be off the market. Polypropylene mesh used for transvaginal prolapse should never have been put on the market. I stand by that. For selected individuals who have failed standard treatment -- that's what we've gone through ad nauseam today -- there may be a role. I was abbreviating what we've talked about today.

Q. And you stand by that statement with the caveats you made today in your deposition; is that fair?

A. That is correct. This here does not go into all of them. I did say in selected individuals. With selected individuals is what we have talked about today.

Q. Got it. Now, on the first page of the interview, Doctor, it says that you reported that no one in the urology department at the Mayo Clinic used polypropylene transvaginal mesh for prolapse. Do you see that?

A. Yeah. And, actually, that's -- that's correct, but short. No one in the urology or GYN at

Page 287

Mayo use meshes for prolapse transvaginal.

Q. So that was my question to you. Does anyone, in the urogynecology division of the Mayo Clinic, use transvaginal mesh to treat pelvic organ prolapse?

A. No. In 2005, when they came out, there were roughly six or seven of us on staff at that point in time. All of us independently, without a discussion, elected not to use it. So that is a correct statement, and they misspelled my name, too.

Q. So if we look at -- let me just mark Exhibit 19.

(Elliott Deposition Exhibit No. 19 was marked for identification.)

BY MS. GEIST:

Q. Doctor, this is a print off from the Mayo Clinic -- I'm sorry.

A. That's all right.

Q. This is a download or a printed page from the Mayo Clinic site. Do you see that?

A. Yeah, I do. I'm trying to figure out, because I was involved with Mayo's policy on meshes and -- but I was not involved with the drafting of this. But I don't know what --

Q. Okay.

A. -- I don't know what this -- I have not seen

Page 288

this document before.

Q. Well, I'll just represent to you, as you can tell from the date on the bottom right corner, that we printed this out on November 5th, 2014. And on page 2 of the exhibit, it appears to indicate that this is dated August 9th, 2014. Do you see that?

A. Yeah. I don't have any reason to doubt its validity. I just wasn't involved in this, the production of this.

Q. Okay. It says, pelvic organ prolapse at the top, correct?

A. You're on page -- the first page?

Q. I'm on the first page, yeah.

A. Yes, it does. That's what it says.

Q. And, it says, concerned about transvaginal mesh complications associated with treatment for pelvic floor disorders? Here is what you need to know, correct?

A. Yes.

Q. And this is provided by the Mayo Clinic staff, true?

A. Mayo Clinic staff, there is a ghostwriter who interviewed somebody and this was written up.

Q. Okay. At least, according to this statement from the Mayo Clinic, surgical mesh, including synthetic

Page 289

materials, can be used to treat pelvic organ prolapse; do you see that?

A. I don't see that document.

Q. All right. So go with me to the second --

A. I mean, I don't see --

Q. Sorry. Second paragraph, it says, Surgical mesh is a medical device that is used to provide extra support when repairing weakened or damaged tissue?

A. Yep.

Q. Most surgical mesh devices are made from synthetic materials or animal tissue?

A. Yes.

Q. Surgical mesh can be used to treat, and then it says POP, right?

A. Yes.

Q. And it says surgery can be done through the abdomen or through the vagina, transvaginal, correct?

A. That's what it states, yes.

Q. And then, on the second page of the statements from Mayo Clinic, it says, if you are considering treatment for a pelvic floor disorder that involves surgical mesh, be sure to have your health care provider explain all of your options, as well as their possible risks and benefits. In particular, be aware of the risks associated with surgical mesh for transvaginal

Page 290

repair of POP, such as the need for additional surgery due to mesh-related complications. Did I read that correctly?

A. Yes, you did.

Q. But, at least, according to this statement from the Mayo Clinic, as of August 9th, 2014, the surgeons at the Mayo Clinic were still offering transvaginal mesh for the repair of pelvic organ prolapse?

A. Absolutely not. No one has. No one at Mayo Clinic Rochester has ever put in, to the best of my knowledge, a transvaginal mesh kit.

Q. So where did this statement come from?

A. This is a ghostwriter. This was written up for information for patients. So I had nothing to do with this one. But all of those authors on that Blandon article, I know them. I operate with them daily. And so, you know, they're -- they're giving the warnings because we are contacted. We are inundated with patients calling up, and this is a resource for patients to look at this.

And then we're not -- we're saying, if you're considering pelvic floor surgery that involves mesh, okay, no one at Mayo does that. But patients come from all over the world to the Website for information. But

Page 291

we're saying, whoever wrote this, make sure you've got all of your options and risks, and they go on and on and on here about the potential risks.

Q. Right. But nowhere in this document, Doctor, does it say, Don't use transvaginal mesh for POP repair, does it?

A. Well, that's what the article states, and it states what it states.

Q. Right.

MR. CARTMELL: Where does it say that you're supposed to -- that they use it like you just said in your question?

MS. GEIST: You can't ask me questions.

MR. CARTMELL: Well, you just asked him a question that said --

MS. GEIST: I said you can't --

MR. CARTMELL: -- so as of this time --

MS. GEIST: No, no, no.

MR. CARTMELL: -- Mayo was using it.

MS. GEIST: Stop.

MR. CARTMELL: And there is nowhere in this document that says Mayo was using it.

MS. GEIST: You can't make speaking objections like you are.

MR. CARTMELL: No. I'm just supposed to sit here

Page 292

and let you ask questions --

MS. GEIST: You can ask your own questions if you want.

MR. CARTMELL: -- that misstate evidence.

MS. GEIST: You can ask your own questions if you want. Be my guest.

MR. CARTMELL: I don't get that.

BY MS. GEIST:

Q. So my question was, Doctor, is that -- is that the accurate site for the Mayo Clinic, mayoclinic.org?

A. Yeah. This is for patient access. But myself, Dr. Lithner, in our department of female urology, Dr. Klingele, Dr. Ochino, Dr. Trabuco, and I believe there is another gynecologist who has never implanted it. So this isn't information for patients who contact the Web. It's not. If they come into Mayo, they're not getting the mesh.

Q. Well, and there is nowhere in this statement, on behalf of the Mayo Clinic, as it states by the Mayo Clinic staff, there is nowhere in here that says, by the way, we don't agree with the implant of transvaginal mesh, we don't use transvaginal mesh, or we think you, patient accessing our site, should not use transvaginal mesh? There is nowhere in here that states that, is there?

Page 293

A. Well, there is no statement of support either.

Q. Well, there is a statement that says, Surgical mesh can be used to treat pelvic organ prolapse through the vagina. And if you're considering this transvaginal repair, talk to your doctor about the risks and benefits. That's what it says, correct?

A. I -- I can completely support that the document says surgical mesh can be used to treat pelvic organ prolapse. I agree with that. It can be. It's not a statement of support.

Q. Well, you have -- I understand your interpretation of that.

MR. CARTMELL: I'll object and move to strike the statement of counsel. Ask him questions if you want to.

MS. GEIST: I am. And if you would stop interrupting me, we would get along a lot better today. You're making your own statements.

BY MS. GEIST:

Q. Doctor, I want to move on to some of the specific opinions in your report that we didn't talk about already. Do you need a break before we move on?

A. No. Let's keep going.

Q. Okay. Okay. Let me start, Doctor, with -- the videographer is signaling us again.

MS. GEIST: Are we okay?

Page 294

VIDEO TECHNICIAN: (Inaudible.)
BY MS. GEIST:
Q. All right. Doctor, let me start with a discussion in your report relating to degradation. We talked a little bit about that before?
A. Correct.
Q. And I think you told me earlier, and correct me if I'm misstating it, that, while polypropylene mesh is polypropylene -- polypropylene mesh, degradation does not occur in all polypropylene mesh?
A. I never stated that.
Q. All right. So then here is my question. Do you still use polypropylene-made urethral slings to treat stress urinary incontinence?
A. No.
Q. Have you ever?
A. Yes.
Q. And how about your colleagues at Mayo? Do they continue to use polypropylene midurethral slings to treat stress urinary incontinence?
A. My colleague in urology used mesh slings for about a year or two starting in 2003 or 2004. She felt it should never have been done and she stopped using it back then. I continued using it longer. But she stopped using it. I cannot speak to what my

Page 295

urogynecology colleagues, what they use.
Q. So the opinion in your report that polypropylene mesh in the Avaulta products degrades and is not inert, does that apply to polypropylene used in slings?
A. Well, I think polypropylene has to be looked at the specifics of the product. From everything I have read and the literature that we have quoted, polypropylene, in the human body, degrades. I don't think that's even a point of discussion. We can go through the articles that talk about that.
Q. Well, let me ask you a question. I don't mean to interrupt you. But let me ask you a question about what you just said. You're providing expert opinions in three plaintiffs' cases tomorrow, correct?
A. I believe so, yes.
Q. Did you see or observe any degradation in the polypropylene mesh they had implanted?
A. Absolutely.
Q. Okay. So we'll talk about -- we'll talk about that more tomorrow. Do you consider yourself to be an expert in the human body's response to polypropylene?
A. As it pertains to implantation in the human body relative to female organ prolapse and incontinence, yes.

Page 296

Q. So do you consider yourself to be a physiological expert in how the body actually reacts to polypropylene?
A. I would say, yes, based upon my experience, my review of the literature, surgical experience, yes, I am. I see it on a daily basis.
Q. Is there any article, Doctor, or anything in the literature that has said that polypropylene cannot be used in the human body to correct pelvic organ prolapse or stress urinary incontinence?
MR. CARTMELL: Object to the form.
MS. GEIST: When in doubt.
MR. CARTMELL: I mean, I don't get it, anything in the literature.
BY MS. GEIST:
Q. Well, is there any -- anything in the literature, any medical article, that has said polypropylene cannot be used in the human body to treat anything, or pelvic organ prolapse, in particular?
A. Well, when you state anything, that's very, very broad. If we want to just focus on just the urinary tract or reproductive tract, for lack of a better phrase, there are hundreds of articles that warn against its use and the complications and the devastating nature of it. Do they come out and use that

Page 297

specific language? They probably don't use those exact words. But they will state over and over, and I can find those articles, that there is limited data to support their use.
Q. Even though polypropylene-based products have been used for decades and decades in different medical device applications?
A. Well, I'd have to ask, are those the same grade that's put through the vagina? Is it in contact with the vaginal flora, lacto- -- lactobacillus, does it have arms going through the vagina, through the obturator foramen, through the buttocks? So we have to be very, very specific in our question and the answer.
Q. Is it your opinion that the specific grade of polypropylene in the Avaulta products has resulted in pain?
A. Yes.
Q. And what do you base that on?
A. My experience of seeing patients in the clinic, my research on the data here of, you know, the national meetings, international meetings, talking with colleagues. Because it's not just my experience. It's also the experience of all of my urogynecology colleagues who arguably see more of this than I do. So, by all means, we see it, the pain.

Q. So maybe my question was bad, Doctor, but have -- what evidence or article can you point me to that specifically links up the use of polypropylene with pain? Do you understand my question?

A. No. No, I do. If we want to go down -- you know, let's just say -- just here. I'm just looking at this, Clave, et al., polypropylene is not inert. That's an abbreviation of the title, okay, but he's going through the complications that happen. Complication is pain. Pain is a reflection of inflammation. Inflammation is a response to degradation. Okay. Mamy, et al., correlation between mesh shrinkage and infection of implanted synthetic meshes. And this is in the animal model. You know, yeah, there is an extensive amount.

Q. All right. Well, let's look at that. You want to bring up Clave. Do you have a copy of Clave?

A. Yes, I do.

Q. Because when you talk about degrading and not being inert, you're citing specifically to Clave, correct?

A. That was one of them. My expert report has, when we're talking about degradation of the product, Liebert, et al.; Ali, et al.; Zhong, et al.; Castello, et al.; Mamy, as I already mentioned; Smith, et al. --

again, we can go on -- white, et al. I have it in here.

Q. Well, let's talk about Clave, first of all?

MR. CARTMELL: Clave.

BY MS. GEIST:

Q. Clave, is it Clave?

A. Clave, yeah. He's part of the French group.

Q. Oh, I see that. It's Clave. Okay. So Clave in the article entitled, Polypropylene As a Reinforcement in Pelvic Surgery is Not Inert?

A. Correct.

Q. Colon, Comparative Analysis of 100 Explants, that's what we're talking about, correct?

A. Correct.

Q. And Clave notes that this is the first study to evaluate synthetic implants used in a vaginal approach for pelvic floor reinforcement; that's what it says?

A. That is correct.

Q. And this was published in 2010?

A. Well, it was received in '09, published online January of '10.

Q. And he admits, if you look in the conclusions part of the study, he admits, in his study, that there is quite considerable medical literature that has concluded and demonstrated that polypropylene is, in

fact, inert?

MR. CARTMELL: Object to the --

BY MS. GEIST:

Q. Do you see that?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. I don't see. I vaguely remember what you're talking about. Yeah. It says, This study, however, brings into question the prevailing understanding of polypropylene as inert when it comes to transvaginal.

Q. All right. So up --

MR. CARTMELL: Are you --

BY THE WITNESS:

A. Now, you interrupted me.

Q. Go ahead. No. I'm sorry. I didn't mean to.

A. So this study --

Q. I'm getting tired.

A. -- is one of the landmark studies of saying, Wait a second, people. What we have been told, what is in the IFUs, what the industry has told us is actually not true. This thing is not inert. It is ert.

Q. All right. So -- I'm sorry. Go ahead.

A. It is active.

Q. Right. So Clave is saying, in 2010, he's acknowledging that all of the studies that came before

found that polypropylene is inert, right?

MR. CARTMELL: Object to form.

BY THE WITNESS:

A. No. That's not true. And even if that's what they state, you have papers in 1976, Liebert, et al., talking about polypropylene degradation in their studies, White from 19-, also, the '70s. So they're saying this and specifically vaginal floor repair.

And you have to look at the Ostergard's paper, I don't know when Ostergard's paper came out, talking about it is not inert, too. I don't know, again, when that one came out. That was 2011. Excuse me. So that was after that. So I don't think --

Q. Okay. And you know what? That was my bad question.

MR. CARTMELL: Were you done?

BY MS. GEIST:

Q. So let me -- let me state it again.

His paper in 2010 is the first paper to provide contrary evidence that characterized polypropylene as inert in the context of its use in the vaginal application?

A. Yeah. What they're stating here -- again, I have not gone back and looked at the dates of other studies that have come out. And Klosterhalfen and

Page 302

Klingele have studies, but that's in abdominal wall hernias. But I'll assume, which is never a good thing to do, that they are accurate in saying -- we're saying, hey, everybody, there is an issue here that we are unaware of. And I will trust that they're accurate, but they must have done a literature search.

Q. Okay. And I should have been more precise. We're talking about polypropylene used in -- in the vagina as a method for pelvic floor reconstructive surgery. So that's what we're talking about?

A. For transvaginal implantation, correct.

Q. Yes. Okay. So Clave acknowledges that this is contrary to the evidence that has come before looking at that specific application, looking at polypropylene as being inert in the use of transvaginal mesh. He acknowledges that, correct?

A. I'm sorry. Can you repeat the question or read it back?

Q. Sure.

A. I'm sorry.

Q. I'll actually read it. Clave says, The study provides evidence contrary to published literature characterizing polypropylene as inert in such applications, and that's referring to synthetic implants used in a vaginal approach for pelvic floor

Page 303

reinforcement?

A. Correct. I agree with that statement, yeah.

Q. Okay. Thank you. I should have just read it from the beginning to make things simpler. Now, Clave, in this study, performed three types of tests, correct?

A. I would have to go back and look at the specifics. I remember he did fairly exhaustive research on it, but I can't say it's three. Scanning, electron microscopy, chemical analysis, statistical analysis, and then infrared spectroscopy.

Q. Yeah.

A. So -- and a histological analysis, so he's done a lot more than just that.

Q. All right. Well --

A. He's done a lot.

Q. Okay. He looked at 100 explants; is that correct, in this study?

A. Yeah. Based upon the title, 100 explants.

Q. Okay. And it's also in the body of the paper, right?

A. Correct.

Q. And it says -- let's see. I'm trying to use the acronyms. He performed the scanning electron microscopy, SEM, right?

A. Correct. Yeah. That's looking for physical

Page 304

evidence for just the degradation cracking of the product, for lack of a better phrase.

Q. He did a chemical analysis, which he referred to as FTIR, correct?

A. Yeah. And that's a study just looking at -- and it's oversimplified, but is something being released, is there information around it, those types of things.

Q. Okay. And then he also did something he called DSC or differential scanning?

A. Yeah. And, again, that -- that -- he's doing some pretty advanced stuff here, but he's just looking at the morphology of the polymer, of the polypropylene polymer -- sheesh, polypropylene polymer. Again, that's involved with degradation breakdown changing of the sub- -- of the material.

Q. It's like a tongue twister today.

A. I'll give that one. That's a tough one.

Q. Now, two of his three tests that we just discussed did not actually show any degradation in this study, true?

A. Again, I would have to look at the specifics of the study. If you support that as being true, I'll follow along with that.

Q. Okay. Well, I'm happy to have you look at it,

Page 305

but --

A. I don't think you are, because it will take you a long time. This is a detailed paper. This is a big paper, so...

Q. I hear you, but this is one of the main things that you cited in your expert report.

A. Okay.

Q. So I kind of thought you'd be prepared to talk about it?

A. I am.

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. I have written -- reviewed 509 papers, so I will now read this one then, and that's going to take some while, as per your permission.

MR. CARTMELL: Please do.

VIDEO TECHNICIAN: Is it okay if I go off real quick? I need a file break.

MS. GEIST: Oh, yeah. Absolutely. That's a good idea, and then the doctor can have time to read the article.

THE WITNESS: I'll stop reading. I'll read on camera.

VIDEO TECHNICIAN: We're off the record. The time is 4:39 p.m.

(A recess was had.)
VIDEO TECHNICIAN: We're back on the record. The time is 4:52 p.m.
BY MS. GEIST:
Q. Okay. Doctor, we were talking about the Clave article before we took a break, and I think you said you would need an opportunity to review the article in detail and in full before you could answer my question about whether two of his three tests did not show degradation?
A. Correct.
Q. Okay. In the interest of time, I'm going to move on and skip to a couple of other things I'd just like to point out to you in the article and ask if you considered them?
A. Okay.
Q. Okay. Did -- did you at all consider whether the degradation that was observed in one of the three tests that Clave performed was actually grooves in the biofilm?
A. Well, I, by all means, considered the multiple different reasons for the possibility of a false-positive study. However, when you look at the actual photographs on page 265, I mean, it demonstrates fractures in it. That is not biofilm. That's a true

fracture.
Q. Okay. So you considered but disagree with the thinking that the cracks or the groves or the fractures could be the biofilm?
A. Yes.
Q. Is that fair?
A. I'm sorry.
Q. Yes?
A. No. I agree with that, and I've heard that argument multiple different times. I think it's a legitimate argument to look at; however, when these are washed appropriately, I believe the data shows that that is not a result. So that is not causing a false-positive study.
Q. Okay. Fair enough. So if you look at page 269 of Clave under Conclusion --
A. Okay.
Q. -- under the third paragraph there, he notes, Several hypotheses persist concerning the nature of polypropylene in vivo degradation? Do you see that?
A. Correct.
Q. Is he right that there are several hypotheses that still persist?
A. Well, I think in 2010 or whenever he wrote this -- remember, he's the first person to come out with

this. Subsequent there have been other authors talking about degradation.
Q. Okay.
A. So at that point in time, as being the first author, he's going to say there, We're trying to figure this thing out.
Q. Right.
A. So you have several possible etiologies of this.
Q. Okay. But a hypothesis, Doctor, whether that term is used by a medical doctor, a scientist, a hypothesis, by definition, means something that is not proven, correct? It's an idea? It's a theory, but it's not proven; is that correct?
A. Yeah. I mean, I think that's probably a fair assessment at that point in time when this was written. Yeah, there are several evolving theories as far as why this is occurring.
Q. All right.
A. And that's what they wrote in 2010.
Q. Okay. And that's fair. So the paper is about theory. It's nothing that's proven?
A. I disagree. They're not -- they're saying this product degrades, period. Why it degrades is up for discussion.

Q. But it didn't degrade using two of the three tests that Clave put the materials through?
A. But it degraded in one of them at least.
Q. On page 266 of his article, does he also state, in the second paragraph, several hypotheses concerning the degradation of the polypropylene are described below. None of these particular direct oxidation could be confirmed in this study. Does he also state that?
A. I don't see where you are; however, I listened to what you had to say because I didn't know which column you were in. But, again, this is a landmark paper saying, Everybody, this product is not inert. It degrades. We're trying to figure out why.
Q. Well, the why is sort of important, right, because the why would determine whether or not degradation would occur in a particular woman, for example?
A. The why is very important. This one paper might not be able to answer all of the questions, and that's why I have to look at the totality of knowledge out there.
Q. Did --
VIDEO TECHNICIAN: Counsel, your mic.
MS. GEIST: Sorry.

Page 310

BY MS. GEIST:
Q. Did you look at any other articles looking at the Clave study, in particular?
A. I'm sorry. Looking at -- did I look at the other articles in reference to the Clave?
Q. Yeah. So did you look at it with any other -- strike that.
Did you look at any other papers that actually discussed the Clave article in particular?
A. Well, I don't know if I could look at ones that discussed it. I would have to go back and look at each one and reference it. It's a very popular manuscript to go to. I mean, but the other ones, Ostergard looking at degradation; Coda, C-O-D-A; Costello; Cozad; Sternschuss, S-T-E-R-N-S-C-H-U-S-S -- and the list goes on -- Ali, et al.; Zhong, et al. I don't know if I mentioned Costello or Mamy. But, I mean, there's like 20 -- if we keep going, 20 articles at least that are building upon Clave's original work.
Q. Did -- did you look at the De Tayrac, and I may be pronouncing that wrong, the De Tayrac article from 2011 that actually looked at what Clave did?
A. Yes. I looked at De Tayrac. He's written multiple articles.
Q. I'm talking about the De Tayrac article

Page 311

entitled, Basic Science and Clinical Aspects of Mesh Infection in Pelvic Floor Reconstructive Surgery?
A. Yes. I've looked at that one. I have that one.
MS. GEIST: Okay. Let me mark it. And I have no idea where I am with exhibits, so maybe the court reporter can help me out.
THE REPORTER: I think 20.
MS. GEIST: I'm sorry?
THE REPORTER: 20.
MS. GEIST: 20, thank you.
(Elliott Deposition Exhibit No. 20 was marked for identification.)
BY MS. GEIST:
Q. Doctor, let me hand you the De Tayrac -- sorry.
A. I have a copy.
Q. Let me toss it to you. Let me give a copy to counsel. Thank you. So you've heard of Dr. De Tayrac. You've read several of his articles I think you indicated?
A. Yes. I know him by reputation at various different meetings.
Q. And did you consider this particular paper in reaching your opinions relating to degradation?

Page 312

A. Yes. It should be in my report. I have a copy of it here with me. So I would assume so.
Q. And De Tayrac, if you look at page -- I think it's 778. Again, it's one of those weird numbering things. 778 is on the fourth page of the De Tayrac article?
A. Yes. I'm there.
Q. Okay. And he notes, Using the same model of mesh infection, we also experimentally tested Clave's conclusion regarding a correlation between infection and polypropylene degradation. Do you see that?
A. Yes, I do.
Q. And then it goes on to describe what they actually did. They implanted polypropylene mesh in Wistar rats and the mesh were explanted and examined, correct?
A. There we have to be more specific. They implanted it in an incisional abdominal hernia in the rats.
Q. Okay. Fair enough. I'm trying to summarize.
A. And inoculated it with E. coli, which all of those are very important factors in this.
Q. And he concludes, at the end of that discussion, that they also observed signs of superficial degradation and transverse cracks, but these appeared to

Page 313

concern only the biofilm with no effect on the implant thread itself?
A. Yeah. And that's what the study found, which is, to me, completely immaterial, because, number one, it's not implanted in the vagina. They inoculated it with E. coli, which, to the best of my knowledge, does not produce hydrogen peroxide like lactobacillus, which is in the Sternschuss article saying that's the most common bacteria in women that produces hydrogen peroxide. So in this study here with E. coli, which is a rare bacteria in adult females' vaginas, that's what finding they had at 30 days.
Q. Doctor, just so I understand your opinions, you don't have the same concern with polypropylene degradation when polypropylene materials are used in a midurethral sing application; is that correct?
A. No. I don't think that is correct. I do have -- I don't use it in my practice anymore because of my concerns because of the complications I saw and because of the complications that have been referred in to me.
Q. Okay.
A. So I do have those concerns.
Q. So you don't agree with the AUGS position statement regarding polypropylene midurethral slings and

Page 314

those slings being the gold standard for the treatment of stress urinary incontinence?

A. I would have to look at exactly what the AUGS said on that. I'm familiar. We looked at the one for prolapse. I would have to look at the ones -- what they said for stress incontinence.

Q. Well, before I show you that, let me just show you what I'll mark as Exhibit 21.

(Elliott Deposition Exhibit No. 21 was marked for identification.)

BY MS. GEIST:

Q. A copy for counsel. This is one of your publications, Doctor. This one was published in -- or actually accepted for publication in the last year, September of 2013, entitled Risk of Repeat Anti-Incontinence Surgery Following Sling Release: A Review of 93 Cases. Do you see that?

A. Yes, I do.

Q. And you note, in your conclusions, that sling release remains an important treatment option in patients with obstruction after anti-incontinence surgery. Did I read that correctly?

A. I don't see where you are. It sounds correct.

Q. Sorry. I'm in the first page of the conclusion in your report.

Page 315

A. Yeah. I agree with that.

Q. And you also state that only a small percentage of patients require repeat anti-incontinence surgery. Do you see that?

A. Yeah. It was 14 percent required a repeat. It's debatable if you call that small or not, but that's what we state there.

Q. That's what you state there, though, correct?

A. That is correct.

Q. And you also conclude, in this article, that the synthetic sling remains a mainstay and an important treatment option for women?

A. That's -- that's what we stated there, yes. It is a -- it is still -- I think I can say this with some accuracy. It is still the most common procedure done for incontinence, but not in my practice it's not.

Q. Okay. But -- and that's -- we're talking about a polypropylene-based sling, correct?

A. That is correct.

Q. And I assume you're also familiar with the Nilsson study that looked at whether there were any issues with a polypropylene-based sling after 11 years?

A. Oh, the Nilsson, yeah. There's -- he published five, ten, 12, 15, and 17 years of TVT.

Q. Right. He actually went all the way out and

Page 316

looked to see whether there were any issues with erosion or adverse events after 17 years, after a woman had a sling in place for 17 years, right?

A. For specifically for the TVT.

Q. Transvaginal mesh?

A. Correct. TVT is the product, transvaginal tension-free mesh for incontinence.

Q. And there were no late-onset erosions or adverse events reported in that study even at 17 years, correct?

MR. CARTMELL: Objection. Misstates the evidence. There was an erosion.

BY THE WITNESS:

A. I would -- I would have to look at the manuscripts. I have reviewed them in the past; but as I stated there, I think four Nilsson studies.

Q. Well, let's look at it together. 22, I think, is the one I'm referring to. I'm sorry. I'm marking it as Exhibit 22.

(Elliott Deposition Exhibit No. 22 was marked for identification.)

BY MS. GEIST:

Q. Just for the record, Exhibit 22 is the Nilsson study published in 2008 entitled, Eleven Years Prospective Follow-Up of the Tension-Free Vaginal Tape

Page 317

Procedure For Treatment of Stress Urinary Incontinence?

A. Yes.

Q. And under -- and the conclusions of this study were that there were no late-onset adverse events found and no case of tape erosion was seen.

A. That is -- that is what they state here, yes, except this was -- came out in other depositions from the medical director at Ethicon that they don't even believe this was the TVT product. They can't vouch for that. That's immaterial to what you're saying, but that's an issue with this paper. But that's the conclusion the authors came to.

Q. Is there -- and that sling, obviously, is implanted transvaginally, correct?

A. Yes. We're talking apples and oranges as far as the angle that's put in, the volume of mesh, the tension that's put on the mesh. It's not going transobturator. It's going suprapubic or retropubic would be more accurate to say.

Q. So that's the reason why we can -- so that's the reason why we don't see any degradation of that mesh in your opinion?

MR. CARTMELL: Object to the form.

THE WITNESS: No.

MR. CARTMELL: This study didn't talk about

Page 318

degradation.
BY MS. GEIST:
Q. Right. Well, this study actually says there were no adverse event whatsoever, and you told me earlier that degradation results in all sorts of adverse events, including dyspareunia?
A. Yeah. We have to -- let's go look at this study carefully. I never said there were no adverse events. There is less mesh put in. So we were not comparing apples to apples here. We're comparing a TVT procedure that's done transvaginal with a plastic sheath over it versus Avaulta. So we can't -- there is no correlation to Avaulta with this.
With this one, as far as complications, I would have to look at the study. They talk about cure rate, which is one aspect as far as complications. Again, I would have to look at all that they state. If there is an erosion or an extrusion, that's a complication.
Q. Agreed. And I'm reading from the study at page 1046 and it says, It is therefore reassuring that we do not find a single case of tape erosion, tissue reactions, or other adverse events during, at the most, up to 13 years of follow-up.
A. I don't see exactly where you are, but that's

Page 319

okay. That's the findings of these authors relative to a possible TVT with plastic sheaths over the arms in a different route that's put in compared to Avaulta, but that's what these findings are.
Q. You said you wanted to see the position statement on mesh midurethral -- midurethral slings or stress urinary incontinence?
A. Well, I said, if we're going to talk about it, I want to see it.
Q. Okay. Let me show it to you briefly. I'm trying to move along. I think I'm up to 23.
(Elliott Deposition Exhibit No. 23 was marked for identification.)
BY MS. GEIST:
Q. This statement, Doctor, was put out as a joint position statement by both AUGS and SUFU, which you've mentioned a few times before. That's the Society of Urodynamics Female Pelvic Medicine and Urogenital Reconstruction, correct?
A. Correct, which I'm a member of and sit on the education committee.
Q. And you're a member of both of these societies, correct?
A. Correct. I don't have any leadership role in AUGS, though.

Page 320

Q. Okay. And the position paper put out by these groups states, at the top, the polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women. Do you agree with that?
A. Well, let's take it sentence by sentence. The polypropylene mesh midurethral sling is the recognized worldwide standard of care in the surgical treatment of stress urinary incontinence. I think that is somewhat debatable. It is, I think, no question probably the most common implantation done now. Many in the society don't use meshes anymore. We are a member of the society. So it doesn't mean that everybody is in support of it, but I can argue that it is the most common procedure done.
The procedure is safe, effective, and improved the quality of life for millions of women. I can't necessarily argue with that. However, what it doesn't also say is the complications that have been seen. Millions of women may have been benefitted, but how many have been injured?
So, you know, the way they state it, that's -- yeah, I can -- it states what it states. How could they

Page 321

show me data? Do we have the studies on millions of women? No. We have the studies, you know, a hundred here and a hundred there. So there is no data to support it's helped millions of people. Millions have been sold.
Q. So you think the statement put out by AUGS and SUFU is a formal position statement and it's not based on data?
A. Well, show me the data. Show me where a study with millions of women.
Q. Well, we just looked at the Nilsson study, which looked at women who had slings implanted and looked at women not 17 years later, correct?
A. Mm-hmm.
MR. CARTMELL: No. We didn't look at the 17-year study.
MS. GEIST: Oh, we looked at the 11-year study?
MR. CARTMELL: Right.
MS. GEIST: Sorry.
MR. CARTMELL: And the reason I objected is because the 17-year shows the erosion. I just didn't want it to look like I was trying to jack with you.
MS. GEIST: That's fine.
BY THE WITNESS:
A. Yes. That study, in a very high-volume center

Page 322

of an individual who was involved with the inventor of the TVT and arguably one of the best surgeons in the world for this, that is the results that they have found. But that does not correlate to everybody else's results.

Q. Well, how about the Mayo Clinic? Doesn't the Mayo Clinic discuss sling procedures and actually state that using surgical mesh is a safe and effective way to treat stress urinary incontinence?

A. I would have to look at -- but, again, I didn't write that article. I don't use -- no one in urology uses mesh slings.

Q. Who is Dr. John Ochino, O-C-H-I-N-O?

A. He is a urogynecologist.

Q. Is he with Mayo?

A. Yes.

Q. And he's a colleague of yours?

A. Well, he's in urogynecology.

Q. Has -- have you seen his YouTube video where he states that sling procedures to treat stress urinary incontinence are safe and effective and have minimal risk associated with mesh complications?

A. I have not seen his video, no.

Q. At least as of last year, though, Doctor, referring back to your own article that we looked at

Page 323

before, the risk of repeat anti-incontinence surgery --

A. Yes.

Q. -- you stated, in that article, that synthetic slings remain an important treatment option for women experiencing stress urinary incontinence, correct?

A. Yeah. But that's not -- that's just stating that it is used frequently. That's all that is stating.

Q. Well, it says it remains an important option. Do you disagree with that, that it should be offered as an option?

A. It is an option. I don't do it, but it is an option out there.

Q. And certainly you wouldn't say that the doctors who offered that option are not performing according to the standard of care, would you?

A. No, I'd say --

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. I would say that the pendulum is swinging anti-mesh. And so right now they're being done. What's going to happen a few years from now, I don't know. The same thing with pelvic organ prolapse.

Q. Let me show you, Doctor, one of your other articles that I thought was of interest. I think I'm up to 24.

Page 324

(Elliott Deposition Exhibit No. 24 was marked for identification.)

BY MS. GEIST:

Q. Do you recognize this article, Doctor?

A. Yes.

Q. I'm trying to give a copy to counsel.

MR. CARTMELL: Thanks.

BY MS. GEIST:

Q. This is one of the articles you mentioned to me earlier, Doctor, when we talked about some of your review of the different types of meshes available in the sling surgery?

A. Yes. That's correct.

Q. And this is an animal study, correct?

A. Yeah. It's a rabbit study we did.

Q. And this was published back in 2003?

A. Excuse me, with work starting in 2001 or so, yes.

Q. And you looked at slings of different types of materials, including polypropylene slings, correct?

A. That is correct.

Q. And each rabbit had different types of slings implanted? Some of these were autologous and some were synthetic?

Page 325

A. Yes. We put in human, cadaveric, porcine, polypropylene, porcine dermis, SIS. We put, as I recall, five.

Q. And you note in this study that the results of this study support the use of polypropylene mesh for sling surgery relative to other nonautologous materials, correct?

A. Yes. And this is a very good one. I'm glad you brought that up because this is a study we did very early on looking at the product and issues. And we raised issues in the discussion that polypropylene mesh gained stiffness with time. At that point in time, we thought that was a good thing, and that's what we wrote in our conclusion. But this is in 2003.

Q. Right.

A. Sine there's been a vast amount of data gathered we're actually realizing that's not a good thing.

Q. And, in your own words, as you've just indicated, in this study, you say, More important than tensile strength is material stiffness. The stretching of the suburethral sling with time is a much more likely scenario than breakage and it may be partly responsible for the reemergence of symptoms following a successful anti-incontinence procedure. So, in other words, you

conclude from this study that the stiffness seen in polypropylene mesh is a positive or a good thing?

A. Yeah. And, at that point in time, I agree. And I stand by the arguments that we proposed here. But what we originally thought, and individuals like Chris Winters, when he came to Mayo, raised this as one of the early papers describing the mesh problems. We had our facts correct. Our interpretation of those facts I would have to say, in the 12-week model, was not correct.

Q. Well, what about your investigation in the same study, Doctor, regarding the issue of shrinkage. You looked specifically at the issue of shrinkage with polypropylene mesh in this study, correct?

A. That is correct. In the 12-week transabdominal model in a rabbit, we did.

Q. And you concluded, from this study, that polypropylene mesh did not demonstrate a significant decrease in surface area compared to the other sling types; in other words, no shrinkage per your own study, correct?

A. Yeah. At 12 weeks, in the rat model -- excuse me, in the rabbit model without the contamination in the vagina. I think others have come along and shown that our data does not correlate to other things.

Q. Well, flipping quickly to that issue, shrinkage or contraction, that's one of the opinions in your report?

A. Yes.

Q. I assume you would agree with me that there is a normal amount of contraction and shrinkage after a medical device is implanted due to the normal and expected healing process?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Well, you say a medical device. Certain medical devices have no contraction.

Q. Well, it's not atypical or abnormal or unexpected to see contraction and scarring after a medical device is implanted; is that true?

MR. CARTMELL: Object to the form.

BY MS. GEIST:

Q. The wound healing process needs scarring and inflammation. It's part of the normal process?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. I disagree. Artificial hips don't have any contraction.

Q. Are there many medical devices that do have scarring and inflammation after they're implanted and

it's needed for the body to heal?

A. I don't know of any that scarring and contraction is actually a good thing. Heart valves can't do that. I mean -- so, no, I don't know of any.

Q. So I just want to make sure I understand. It's part of the body's normal healing process. You disagree that scarring and inflammation is part of the normal process that the body goes through to heal itself after surgery when a device is implanted?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Well, the body's natural response is to heal itself and to decrease inflammation. It is normal with any surgery to have that to a certain extent that then heals up and finishes and that process stops. It is abnormal for that process to continue on.

Q. You looked at inflammation specifically with polypropylene mesh in another one of your studies, correct?

A. That is correct.

Q. And you looked at inflammation and scar formation, true?

A. Correct.

Q. And didn't you conclude in that study that the inflammation and scar formation seen, after the

polypropylene mesh was implanted, was actually a good thing and helped the in-tissue growth process?

A. Our conclusions that we reached in 2006, on that specific study, we attributed that. We thought that was a good thing. I have subsequently been proven wrong.

Q. Well, in your own -- let's just mark it quickly so we know what we're talking about. I think I'm up to 24.

MR. CARTMELL: 5.

MS. GEIST: 5, but who's counting.

(Elliott Deposition Exhibit 25 was marked for identification.)

MR. CARTMELL: Man, you've used a lot of exhibits.

MS. GEIST: Well, I think it's helpful to look at what you're talking about.

BY MS. GEIST:

Q. Doctor, here is Exhibit 25. This is another one of your studies that we mentioned earlier entitled, Time-Dependent Variations in Inflammation and Scar Formation of Six Different Pubovaginal Sling Materials in the Rabbit Model. So, again, this is another animal study looking at different types of sling materials, including polypropylene sling after implantation, correct?

Page 330

A. Yeah, in a 12-week model. I think we had six weeks and 12 weeks. So, roughly, three months.
Q. And you conclude from the study that polypropylene mesh compared to the other types of meshes that you looked at in this study had low inflammation, correct?
A. Yeah. The high fibrosis and low inflammation in the rabbit transabdominal model at 12 weeks.
Q. And you conclude that not only did polypropylene mesh have lower inflammation than the other materials you've looked at, but that the fibrosis and scarring noted with polypropylene mesh may also contribute to a more lasting repair?
A. That was our conclusion. And then I go on and warn, Urologists performing this procedure should be aware of the time-dependent tissue reactions when choosing a sling material. As I mentioned, we had -- we reached certain conclusions, which, now, I think are actually incorrect. And it's been pointed out by other authors that we had our facts right, our interpretation wrong.
Q. Well, you said -- you said a couple of times that these studies were done in rabbits, correct?
A. Correct.
Q. Would you agree with me that it would be more

Page 331

important to see what's actually going on in the human body? The best way to do this is to look into the body in vivo, see what's going on?
A. Well, I mean that would be the ideal is actually what happens when it's implanted in women.
Q. Did -- did you consider, in reaching your opinions relating to contraction and shrinkage, the Dietz study?
A. The Dietz study?
Q. Yeah.
A. I don't recall. I'd have to look at that. I do not recall that name. D-I-E?
Q. D-I-E-T-Z?
A. Mechanical Properties of Urogynecologic Implants.
Q. No. Dietz is the European urogynecologist, and he published a study entitled, Mesh Contraction: Myth Or Reality. Did you review that?
A. Okay. I do not have that in -- on my list of ones I reviewed. I'd be happy to take a look at it, though.
(Elliott Deposition Exhibit No. 26 was marked for identification.)
BY MS. GEIST:
Q. I'll be happy to hand it to you. Here you go.

Page 332

If you look with me at it quickly, Doctor, Dietz actually looked at the issue and phenomenon of mesh contraction or shrinkage by looking at the mesh via ultrasound and concluded that there was no contraction after 18 months?
A. That is what this one study states. But if you look at my actual report, I've got a list of 12 or 15 articles that state opposite to that.
Q. Well, you didn't consider this study in forming your opinions relating to mesh contraction and shrinkage; is that fair to say?
A. That is --
MR. CARTMELL: Objection to form. Go ahead.
BY THE WITNESS:
A. That is -- that is true.
Q. Did you look at Bard's soft mesh study in forming your opinions?
A. I don't know what study that is.
Q. Did you look at the Pierce study? It showed a shrinkage of less than 10 percent?
MR. CARTMELL: With Avaulta?
MS. GEIST: You're asking me a question?
MR. CARTMELL: Yeah.
BY THE WITNESS:
A. Piece, Biomechanical Properties of Synthetic

Page 333

and Biologic Graft Materials. Is that the article you're referring to?
Q. No. I'm referring to Piece, 120-day Comparative Analysis --
A. Okay.
Q. -- Of Adhesion Grade and Quantity Mesh Contraction and Tissue Response?
A. No. I have not seen that article.
MS. GEIST: How much time on the video?
VIDEO TECHNICIAN: 6 hours, 43.
THE WITNESS: Half and half. The half and half, it's right in the cup. Sorry. Sorry.
BY MS. GEIST:
Q. Doctor, one of the -- one of the opinions you set forth in your report is that the blind passage of the trocar used to implant the Avaulta products is unsafe, correct?
A. That is correct.
Q. Are there any other procedures that you, as a urologist or a urogynecologist or a gynecologist, perform in women that are considered to be blind, blind passage; in other words, you have to use palpation?
A. Not to the extent and the distance of these.
Q. But you still use procedures or engage in procedures that would be considered to be blind passage

Page 334

such as a D&C, for example?
A. I don't do D&Cs.
Q. All right. So gynecologists do D&Cs, correct?
A. Some of them do, I suppose.
Q. Do you understand that they need to use palpation in order to apply the correct amount of tension or pressure on the needle?
A. I've never performed one, so I can't speak to that.
Q. Can you give me any other examples or procedures that you may have performed that are considered to be a blind procedure or, in other words, where you need to use palpation?
A. Not anymore.
Q. What about the robotic procedures that you perform? Are those not considered to be blind procedures in some respect?
A. It's all under direct vision.
Q. What about the laparoscopic procedures that we've talked about?
A. Again, that's all under direct vision.
Q. What about the sacrospinous?
A. Sacrospinous fixation, I don't -- I don't perform that procedure.
Q. Did you ever perform it?

Page 335

A. I performed them as a fellow under the staff guidance. However, the staff never let me pass the needles through the sacrospinous. Even with that it's a small degree of passage. But he didn't feel it was safe for someone learning to do, so I never did pass it.
Q. Well, but some doctors do it. It goes through the deepest recesses of the vagina; isn't that true?
A. Yeah. But that's with a Capio needle.
Q. Right.
A. And you're passing it, perhaps, 2 centimeters, maybe, with your finger back there. That's different than passing a trocar through the obturator foramen or larger passages of several centimeters. It's over 5, 10 centimeters. That's different.
Q. Okay. So you'll agree with me it's considered a blind procedure because it's done by palpation, but it's less than the amount of -- strike that.
You'll agree with me it's a blind procedure because there is some portion of it where you would need to use palpation only?
A. No. I can't necessarily. I mean, there is a minor passage of a minor distance. So very strictly defining it as that, yes. But, again, we're not talking of 10 centimeters of blind passage. And with a Capio needle, your finger is back there and you just pass the needle right onto it, so...
Q. Well, you've recently done some work in developing innovations in autologous sling procedures, correct?
A. Autologous transobturator sling.
Q. And I'm referring to your case report that was published just this year?
A. Correct.
Q. And to implant that autologous sling, you used a trocar, correct?
A. And it would be passed 5 millimeters to, perhaps, 1 centimeter onto your finger behind the obturator bone.
Q. So that's a good example of a blind passage, agree? It's a blind passage procedure using the trocar, true?
A. To a minor degree, yes, that is going to be blind because it's going to be passing it 5 millimeters to 1 centimeter.
Q. And you consider that to be an innovation and another option that you could offer for women suffering from stress urinary incontinence, true?
A. Yeah. That is -- that is an evolving option. We are the world's first to do that. We have to have the data pan out to see if it's going to be a viable option. It appears to be, though.

Page 336

Page 337

Q. Sure. It's a novel technique, as you state in your own case report, but it is used with a trocar and a blind passage?
A. With the caveat that it is a 5 millimeter to, perhaps, 1 centimeter of passage right down onto your finger.
Q. Okay.
A. So it is minimal.
Q. I'm running out of time here, Doctor, so I'm going to try and wrap it up as fast as I can.
Let me ask you some questions about pore size. Pore size is one of the opinions in your report that the pore size of the Avaulta products was inadequate to promote proper tissue ingrowth?
A. Correct.
Q. What do you believe or define as optimal pore size in a mesh product?
A. According to my review of the literature, my experience of taking care of complications in patients, I believe that the pore size ranging between 4 millimeters or so is going to be a lower chance of complications.
Q. Is there a consensus in the literature as to what the optimal pore size should be?

Page 338

A. I believe there is based upon the literature out there, that because the pore size as it's taken out of the box does not correlate to the pore size once it's in the women when there's contraction.

Q. You've never designed a mesh product; is that correct, Doctor?

A. I've been involved in consulting with Coloplast -- excuse me, AMS on theirs, but I'll leave it at that.

Q. Have you ever designed a mesh product?

MR. CARTMELL: Object to the form. Asked and answered.

BY THE WITNESS:

A. Yeah. I've been a consultant on their mesh and their design.

Q. On the design specifically?

A. The shape, the length of it.

Q. How about the pore size?

A. Pore size, I was not involved specifically in the pore size of this product, no.

Q. Have you ever done a study looking at pore size and its impact on tissue integration?

A. I have relied on the work of others as outlined in my expert report.

Q. Can you point to me, Doctor, any study that has demonstrated that a pore size of greater than 2.0 millimeters is superior to a 1.0- or 1.3-millimeter pore size in a mesh?

A. I think when you look at Cobb's study, Klingele's study, looking at various different pore sizes, that -- and probably also Klingele and also looking at the internal documents with Bard where they acknowledge that the pore size has to be larger.

Q. Are you referring to the Bobbie Orr memo that's cited in your report?

A. Yeah. What's cited there, yes, Dr. Ross.

Q. Did you read that memo in its entirety?

A. Yes.

Q. The memo says that the -- what's proposed by Mr. Orr is a hypothesis, does it not?

A. I would have to see it, because I don't have that document with me. I've read it, but I don't have the document with me.

Q. Let me quickly go to the section of your report, Doctor, if you could, with me. Go to the end. On page 35 of your report, page 35 to 39, Doctor --

A. Yes.

Q. -- this section of your report relates to your opinions that Bard failed to disclose pertinent risk information; do you see that?

Page 340

A. Yes, I do.

Q. And I think I counted in this these pages that you said Bard failed to do any number of things, but I think you said Bard failed to do something about 36 times from pages 35 to 38. Does that seem like a fair estimate?

A. Well, without counting it up, just that seems a little bit high, but I wouldn't be surprised.

Q. There is no citations anywhere to any authority for your opinions about what Bard did or didn't do or warned or should have warned of in this section of the report, true?

A. I guess I don't know what you mean citations. I mean, what I have down here is, in my understanding of labeling and warnings and regulations, that Bard is responsible for warning about complications. And so, you know, we could go through each one of those complications and find a manuscript that discusses it. And so I have depositions here talking about them. So I guess I disagree that there's -- there are references listed.

Q. You don't consider yourself to be an expert in terms of what a label should and should not say, do you, Doctor?

MR. CARTMELL: Object to the form.

Page 341

BY THE WITNESS:

A. No. I disagree with that. Based upon -- based upon my experience in dealing with patients for 20 years, dealing with IFUs, handing out patient brochures, I can count up 20 or so different products that I've used the IFU, being a researcher, talking about complications in my manuscripts which you have listed, being on the SUFU Board of Education where we talk about warnings, asked to be speaking nationally/internationally, no, everything I do is about warnings. What I talk to my patients about, the complications I have to see is all about warnings.

Q. Have you ever participated in the drafting of an instruction for use or directions for use for any medical device product?

MR. CARTMELL: Okay. Hold on. I think we're at seven hours according to the -- we're not yet? Okay.

VIDEO TECHNICIAN: About five and a half minutes left.

MR. CARTMELL: Five and a half minutes left. You're in good shape.

MS. GEIST: Oh, yeah. I'm in great shape.

BY MS. GEIST:

Q. Can you answer that question, Doctor?

A. And the question -- let me reiterate it to

Page 342

make sure I've got it correct. Have I ever been involved in the drafting of an IFU? I have been involved in the discussions about complications that can go on IFUs. I have not sat down and written an IFU.

Q. You've never drafted a label or an IFU for a medical device company, true?

A. I have not. In your specific limitations, I have never sat down with a company and written up specifically an IFU.

Q. Are you an expert in the regulations relating to what IFUs should contain or not contain?

A. Yes.

Q. You are?

A. Yes.

Q. What are those regulations?

A. Those regulations are that every -- every known complication, regardless of severity or frequency, need to be reported on an IFU.

Q. So you looked at the Bard IFUs, right?

A. Yes.

Q. And there is, in the adverse event section, a warning relating to erosion, correct?

A. Yeah. I would like to see that IFU, because I have to see all of the IFUs, including the original one. So I would have to look at that. I don't have those

Page 343

IFUs with me.

Q. You don't remember sitting here now talking about these sorts of issues that we've been talking about all day, whether Bard warned of erosion in the IFUs for the Avaulta products?

A. Well, no. That's why we have to go back to my expert report and what I've talked about. The failure to warn to the extent and the severity and the lifelong nature of that, I never saw anything in there to support that.

Q. What regulation says you need to do that?

A. Well, based upon the FDA regulations as far as everything needs to be warned about and the severity and the frequency of it.

Q. What FDA regulation are you referring to?

A. Based upon the FDA Blue Book.

Q. Can you give me the particular regulation or the cite?

A. Yeah. FDA Blue Book started in March of 1991, but updated -- this one is a 3/11/13. It's the guidance for labeling, contraindications of warnings, an adverse reaction is an undesirable effect, all of these have to be reported. Adverse reactions should be listed in descending order according to their clinical significance determined upon their severity and

Page 344

frequency. Provide frequency data from adequately reported clinical studies.

Q. That wouldn't apply to a product that was cleared by FDA through the 510(k) process, would it?

MR. CARTMELL: Object to the form and misstates the evidence.

BY THE WITNESS:

A. Well, absolutely. I mean, the 510(k) is just merely a clearance. It's not an approval of the safety of that product. And so I cannot speak to what information, all the FDA was given and all of the discussions that was going on. But when I read over the IFU, that is what doctors are going to be reviewing, I don't see in there, based upon the FDA Blue Book, adverse reaction, descending order, and provide frequency data.

Q. No. But you just referred to clinical studies, and those are not required through the 510(k) clearance process. You understand that, correct?

A. However, with the 522 where the FDA came back to all of the manufacturers of kits saying, You need to provide us with adequate data, none of those companies, including Bard, could come up with that data and decided to pull their product off the market.

Q. I think what actually the FDA said was, in

Page 345

order to continue marketing and selling the products, you need to engage in clinical trials at this time?

A. Absolutely, and they did not have it.

Q. They did not proceed with the clinical trials, correct?

A. Because they did not have that data.

Q. No. They didn't do it?

A. But I'm correct in that they did not have it.

Q. There were 21 articles relating to the Avaulta products from the time of launch through 2013. Do you dispute that?

A. I would have to look at it. According to my recollection, I have 17 down. So if you have 21, I would not dispute that.

Q. So that's clinical data, correct? That's data from actual product use?

A. Absolutely that is data. But for the reasons of the FDA, when they reviewed them, none of that data was sufficient for the FDA to be appeased.

Q. In this litigation, you're not holding yourself out as an expert in FDA regulations or whether Bard complied with each and every regulation in terms of the IFUs, are you?

A. No. I would disagree. Because, as I mentioned, you know, multiple times to you, all of those

Page 346

various different criteria as far as reviewing the manuscripts, reviewing patients, taking care of patients, education committee, talking about warnings that I have a very good working knowledge of what is required of a product to meet the standards.

Q. So let me just make sure I understand. You don't have any formal education, training, or experience designing a pelvic mesh product; is that correct?

A. Well, no. That's also incorrect.

Q. When have you designed a pelvic mesh product?

MR. CARTMELL: We're at seven hours.

MS. GEIST: Okay. Well, counsel is telling me I need to stop, so...

MR. CARTMELL: I think you asked that last question. If you want him to answer, I think it's already been asked and he told you he consulted on it. But I'll let him answer that last question.

BY THE WITNESS:

A. Yeah. I've been involved as far as with the Interpro as far as the measurements, the design of the product, and that's a pelvic organ prolapse mesh.

MS. GEIST: All right. If you're telling me my time is up, my time is up.

CROSS-EXAMINATION

Page 347

BY MR. CARTMELL:

Q. And, Doctor, I'm going to ask you a few follow-up questions. But let me start by asking you, have all of your opinions that you've offered today been within a reasonable degree of medical certainty?

A. Yes.

Q. Okay. And you've talked ad nauseam about all of the materials that you've reviewed, including literature, Bard documents, you've talked about your experience and training. Do you feel like you have all of the information you need as of this time to offer the opinions that you have offered throughout today's deposition?

A. Yes.

Q. Okay. Now, you were asked, at some length, about 2011 when you sent a letter, I believe, to the FDA supporting a petition by Public Citizen for the Avaulta products that we're talking about here today, among other pelvic organ prolapse, being banned or removed from the market. Is that true?

A. That is correct.

Q. Okay. And, again, that was in 2011. So the Avaulta products that we're talking about today had been on the market for approximately three years, maybe a little longer than that; is that true?

Page 348

A. Correct.

Q. Now, at that time, I think you were asked questions and asked if you were an extremist in your position about pelvic organ prolapse that are transvaginal mesh products like the Avaulta products; do you remember that?

A. Yes.

MS. GEIST: Objection to form.

BY THE WITNESS:

A. Yes, I do.

Q. And, in fact, in your submission to the FDA that you signed off in 2011, I believe it was August; is that correct?

A. August 19th, 2011, something like that.

Q. In your Public Citizen submission that you signed off on in your letter, you admittedly acknowledged that what you were asking the FDA to do, as far as banning the products, was admittedly an extreme position; is that right?

A. Yeah. It was extreme. The extreme word everyone is getting hooked up on. I took it as an aggressive measure to protect women and their bodies. And everyone is getting hooked up on extremism. But as it pans out, I was absolutely right. Jump forward three years.

Page 349

Q. Let me ask you about that. So in 2011, August, you asked the FDA -- and feel free to review Exhibit 14, which was talked about earlier. You asked the FDA, as a urologist practicing at the Mayo Clinic, to ban the product and to require that medical device manufacturers like Bard, who was selling the Avaulta products, you asked the FDA to make them do actually controlled, randomized studies to demonstrate safety, didn't you?

A. That is correct.

Q. And I think you testified that you did that because you didn't believe, at that time, that there had been adequate data to suggest or support that the Avaulta products were safe for women, correct?

A. There was not data to support the use of any, including Avaulta, mesh kits in women.

Q. Now, I will represent to you that only four months later the FDA sent what's called a 522 letter or order to Bard as a manufacturer of the Avaulta products; did you know that?

A. I know a 522 was sent out. I don't know the date on that.

Q. Well, I'll represent to you that it was in January of 2012, just four months after you asked the FDA to ban these products and require the manufacturers

Page 350

to do well-controlled studies to demonstrate safety. Will you assume that for purposes of my questions?
MS. GEIST: I'll just object to the form.
BY THE WITNESS:
A. Yeah. I have no reason to doubt that's accurate.
Q. And just four months later, when the FDA sent a letter to Bard, did you know that the FDA told Bard, like you had said and recommended, that they needed to do well-controlled, randomized studies in order to continue marketing the Avaulta products?
A. I'm --
MS. GEIST: Objection to form.
BY THE WITNESS:
A. I'm aware of that, yes.
Q. And that was exactly what you had asked for, as a part of your submission, just four months before that; isn't that right?
A. That is correct. I feel that my statement there was taking an educated moral stand on the product trying to protect women. So I'm very proud of that document because I think it possibly may have led to some good.
Q. And what is your understanding based on your review of Bard's documents that they produced in this

Page 351

litigation? In other words, when the FDA asked Bard to do controlled studies to try to demonstrate that the Avaulta products were safe, what was Bard's response?
MS. GEIST: Objection to form. Misstates facts.
BY THE WITNESS:
A. My understanding of the situation is just as you mentioned. The FDA asked for certain documentation, certain studies. Bard came forward with incomplete data and then elected not to pursue the studies that would allow the product to be continued to be sold.
Q. And then Bard actually took the products off the market, didn't they?
A. That is correct.
Q. In other words, since, approximately, 2012, shortly after you asked the FDA to make them no longer sell these products and look into safety studies, Bard decided, themselves, not to do a safety study and took the product off the market. Is that your understanding?
MS. GEIST: Objection to form.
BY THE WITNESS:
A. That is absolutely correct. However, from my angle on it, it is that there were four or five months there that this was continued to be implanted in women and continued to have damage for women. So to me it's a

Page 352

success, but it's also a failure.
Q. And not only did Bard take these products, these pelvic organ -- strike that.
Not only did Bard take these pelvic organ prolapse mesh products off the market, but other manufacturers of those products also took their products off the market; isn't that fair?
MS. GEIST: Objection to form.
BY THE WITNESS:
A. My understanding is that all manufacturers of mesh kits have been pulled off the market because they could not meet the criteria of the 522 as requested by the FDA.
Q. And so now going on several years, these products are not being marketed and sold by Bard, correct?
A. That is my understanding, but I'm continuing to see the complications and will for years.
Q. Now, you were asked several questions about the AUGS, or the American Urogynecologic Society position statement related to pelvic floor disorders; do you remember that?
A. Yes.
Q. Okay. And that's a 2011 document, correct?
A. That was right around the time of the first

Page 353

FDA warning in, what, August of '11.
Q. And that was before the time that the FDA had told the manufacturers that they needed to do safety studies in order to keep marketing their products, correct?
A. Correct.
Q. So this 2011 statement by AUGS, since this statement, there virtually -- there are no pelvic organ prolapse kits still being sold in the United States, correct?
A. That is my understanding. To the best of my knowledge, there are none available.
Q. So this AUGS position statement that you were asked questions about is referring to products, POP kits like the Avaulta products, that aren't even being sold anymore, right?
A. Correct.
Q. And this position statement that you were asked about, this was written by a select small group of authors from AUGS; is that right?
MS. GEIST: Objection to form.
BY THE WITNESS:

Page 354

A. I have no idea who wrote it. Usually this is coming from the board, but I don't know who wrote that. I know for SUFU, members of the board wrote it.

Q. Okay. But you can't tell from this position statement if any of the authors of this document even used the Avaulta products on their patients, can you?

MS. GEIST: Objection to form.

BY THE WITNESS:

A. No, I can't. I can't state that, no.

Q. This position statement certainly doesn't endorse the Avaulta products specifically, does it?

MS. GEIST: Objection to form.

BY THE WITNESS:

A. Avaulta is never mentioned in that one.

Q. And then you were asked also several questions about midurethral slings that are transvaginally placed. Do you recall that?

A. Correct.

Q. Now, your opinions in this case, in your report and during your testimony today, relate to the Avaulta pelvic organ prolapse products, correct?

A. Correct.

Page 355

Q. Okay. This case is not about a midurethral sling, correct?

A. No.

MS. GEIST: Objection to form.

THE WITNESS: It's about Avaulta.

BY MR. CARTMELL:

Q. Okay. And is a pelvic organ prolapse mesh kit very, very different than a midurethral sling?

A. There are many, many factors in there, which we could kind of go down and dissect it out, that it is a different device for a different problem, different locations the mesh is going, different volume of meshes, arms, et cetera.

Q. And you were asked specifically about AUGS again, the position statement, related to the slings. But this position statement doesn't specifically endorse any of Bard's products, does it?

A. No.

MS. GEIST: Objection to form.

BY THE WITNESS:

A. No products are mentioned. And now SUFU is on that one, which I'm a member of the education committee. But many of us -- and there are strong anti-mesh people. So just because the foundation came out with that document, doesn't mean all of its members support it.

Page 356

Q. And you were asked a question about this statement in here that says, at this time, AUGS was saying the procedure is safe, effective, and has improved the quality of life for millions of women talking about slings, not pelvic organ prolapse, correct?

A. That document is very clearly, as it mentions, mesh midurethral slings for stress urinary incontinence, has nothing to do with prolapse.

Q. In fact, you were asked if you agreed with this statement. But in your personal practice, you have now concluded that the risks even of these transvaginal mesh slings outweigh the benefits in your patients, correct?

MS. GEIST: Objection to form.

BY THE WITNESS:

A. Correct. And that is based upon my review of the literature, my interactions with patients who are coming in refusing to have slings put in because of fear of complications, and dealing with the complications of these.

Q. And have you found in your practice, based on your interactions with doctors all around the world in your professional meetings, in your publications, and in your practice, that more and more doctors are like you and now finding that they should not implant even transvaginal mesh slings? Are you finding that that tide is turning?

Page 357

MS. GEIST: Objection to form.

BY THE WITNESS:

A. There's no question the pendulum is swinging back towards native tissue types of repairs because at least then we don't deal with the long-term complications.

MR. CARTMELL: That's all I have. Thank you.

MS. GEIST: You're not letting me go past seven hours.

MR. CARTMELL: Well, I think the Federal Rules are pretty clear, and I did tell you beforehand that, if you were going to do an examination, again, that you should save some time.

MS. GEIST: I'm just making sure I understand your position.

MR. CARTMELL: Okay. And if we need to take it up later, we can.

MS. GEIST: No. That's fine. I just wanted to understand your position. All right.

VIDEO TECHNICIAN: This concludes today's

deposition of Dr. Daniel Elliot. We're off the record. The time 5:58 p.m.

(Elliott Deposition Exhibit Nos. 27 & 28 were marked for identification.)

(Whereupon, the deposition was continued to November 14, 2014 at 8:53 a.m.)

UNITED STATES OF AMERICA)
NORTHERN DISTRICT OF ILLINOIS)
EASTERN DIVISION) SS.
STATE OF ILLINOIS)
COUNTY OF COOK)

I, Jennifer L. Bernier, Certified Shorthand Reporter, Registered Professional Reporter, and Notary Public, do hereby certify that DANIEL S. ELLIOTT, was first duly sworn by me to testify to the whole truth and that the above deposition was reported stenographically by me and reduced to typewriting under my personal direction.

I further certify that the said deposition was taken at the time and place specified and that the taking of said deposition commenced on November 3, 2014, at 9:23 a.m.

I further certify that I am not a relative or employee or attorney or counsel of any of the parties, nor a relative or employee of such attorney or counsel, nor financially interested directly or indirectly in this action.

In witness whereof, I have hereunto set my hand and affixed my seal of office at Chicago, Illinois, this 5th day of November, A.D., 2014.

JENNIFER L. BERNIER, CSR, RPR, CLR
CSR No. 084-004190

TO: Daniel Elliott, M.D.
Re: Reading and Signing Your Deposition Transcript
Date Errata due back at our offices: 12/20/2014

Greetings:
You have reserved the right to read and sign your deposition transcript. Please review the attached PDF transcript, noting any changes or corrections on the attached PDF Errata. You may fill out the Errata electronically or print and fill out manually.

The PDF files open with Adobe Reader. If you need help opening these files, please see the instructions in the cover letter of this email.

Once you have completed your Errata, please print it, sign it, and have the document notarized in the place provided.

When the signed Errata is returned to us, we will seal and forward to the taking attorney to file with the original transcript. We will also send copies of the Errata to all ordering parties.

If the signed Errata is not returned within the time below, the original transcript may be filed with the court without your signature.

Please send completed Errata to:
Tiffany Alley Global Reporting & Video
730 Peachtree St. NE, Ste 470
Atlanta, GA 30308
(770) 343-9696

ERRATA

I, the undersigned, do hereby certify that I have read the transcript of my testimony, and that

___ There are no changes noted.

___ The following changes are noted:

Pursuant to Rule 30(7)(e) of the Federal Rules of Civil Procedure and/or OCGA 9-11-30(e), any changes in form or substance which you desire to make to your testimony shall be entered upon the deposition with a statement of the reasons given for making them. To assist you in making any such corrections, please use the form below. If additional pages are necessary, please furnish same and attach.

Page _____ Line _____ Change _____

_____

Reason for change _____

Page _____ Line _____ Change _____

_____

Reason for change _____

Page _____ Line _____ Change _____

_____

Reason for change _____

Page _____ Line _____ Change _____

_____

Reason for change _____

Page _____ Line _____ Change _____

_____

Reason for change _____

Page _____ Line _____ Change _____

_____

Reason for change _____

Page _____ Line _____ Change _____

_____

Reason for change _____

Page _____ Line _____ Change _____

_____

Reason for change _____

Page _____ Line _____ Change _____

_____

Reason for change _____

Page _____ Line _____ Change _____

_____

Reason for change _____

Page _____ Line _____ Change _____

_____

Reason for change _____

_____

DEPONENT'S SIGNATURE

Sworn to and subscribed before me this ___ day of _____, _____.

_____

NOTARY PUBLIC

My Commission Expires:_____

G

I

M

O

Q

T

U

Z